



Department of Defense Chemical and Biological Defense Program

FY2004-2006 Performance Plan

March 2005

Report Documentation Page			Form Approved OMB No. 0704-0188	
<p>Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p>				
1. REPORT DATE MAR 2005	2. REPORT TYPE	3. DATES COVERED -		
4. TITLE AND SUBTITLE Depaartment of Defense Chemical and Biological Defense Program. FY2004-2006 Performance Plan.			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Department of Defense, Washington, DC, 20301			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited				
13. SUPPLEMENTARY NOTES The original document contains color images.				
14. ABSTRACT see report				
15. SUBJECT TERMS				
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES 136
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified		

Copies of this report may be downloaded from the World Wide Web through the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense Web Site at <http://www.acq.osd.mil/cp> under the reports section as an Adobe Acrobat (.pdf) file.

Cleared for Public Release.
Unlimited Distribution.

DoD CBDP Performance Plan – Contents

Section	Page
1.0 INTRODUCTION.....	1
1.1 Overview of the DoD CBDP Performance Plan	2
1.2 Vision, Mission, Goals, and Values of the CBDP.....	3
1.3 Joint CBRN Defense Functional Concepts and Operational Goals	4
1.4 Performance Plan Methodology	5
1.5 Summary of Key Performance Metrics.....	9
2.0 OVERVIEW: ADVANCED DEVELOPMENT AND PROCUREMENT PERFORMANCE GOALS AND MEASURES.....	14
2.1 OPERATIONAL GOAL 1: <i>SENSE</i>	14
2.2 OPERATIONAL GOAL 2: <i>SHAPE</i>	21
2.3 OPERATIONAL GOAL 3: <i>SHIELD</i>	23
2.4 OPERATIONAL GOAL 4: <i>SUSTAIN</i>	33
3.0 SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES.....	38
3.0 OVERVIEW	38
3.1 CB DEFENSE S&T PLANNING	38
3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM.....	39
3.3 DEFENSE TECHNOLOGY OBJECTIVES.....	40
3.4 <i>BASIC RESEARCH</i> (PROGRAM ELEMENT 0601384BP)	46
3.5 <i>APPLIED RESEARCH</i> (PROGRAM ELEMENT 0602384BP)	56
3.6 <i>ADVANCED TECHNOLOGY DEVELOPMENT</i> (PROGRAM ELEMENT 0603384BP).....	85
4.0 CB DEFENSE HOMELAND SECURITY AND FORCE PROTECTION	103
4.1 WMD Civil Support Team (WMD-CST) Advanced Technology Development... <td style="text-align: right;">103</td>	103
4.2 WMD-CSTS and Installation Protection	104
5.0 DOD CBDP DEFENSE MANAGEMENT PRACTICES	107
5.0 OVERVIEW	107
5.1 CB DEFENSE MANAGEMENT PRACTICES – GOALS AND MEASURES ..	107
5.2 CHEMICAL/BIOLOGICAL DEFENSE (RDT&E Management Support)	108

(INTENTIONALLY BLANK.)

1.0 INTRODUCTION

The Department of Defense (DoD) Chemical Biological Defense Program (CBDP) performance plan provides an assessment of the most recently completed fiscal year (FY04) and outlines performance targets for the next two years (FY05–FY06) of the program. This performance plan demonstrates compliance with the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a process by which the CDPB can measure the effectiveness of the various projects under the CDPB and assesses their contributions to the operational goals and the mission of the program. This process provides a tool for identifying programmatic strengths and weaknesses and aids in the effective oversight and management of the program by providing a tool to assist in making investment decisions.

DoD's management priorities have been defined by near-term operational threats. In the Report of the *2001 Quadrennial Defense Review*, DoD outlined a new approach that tailored the balanced scorecard concept to provide a management framework to help defense managers balance investment priorities against risk over time.¹ DoD has tailored the Balanced Score Concept and outlined four broad areas of risk management that support the Department's vision, mission, and goals. (See **Figure 1**.) DoD pursues an investment strategy that seeks to reduce overall program risk by balancing risk in each of the following areas.

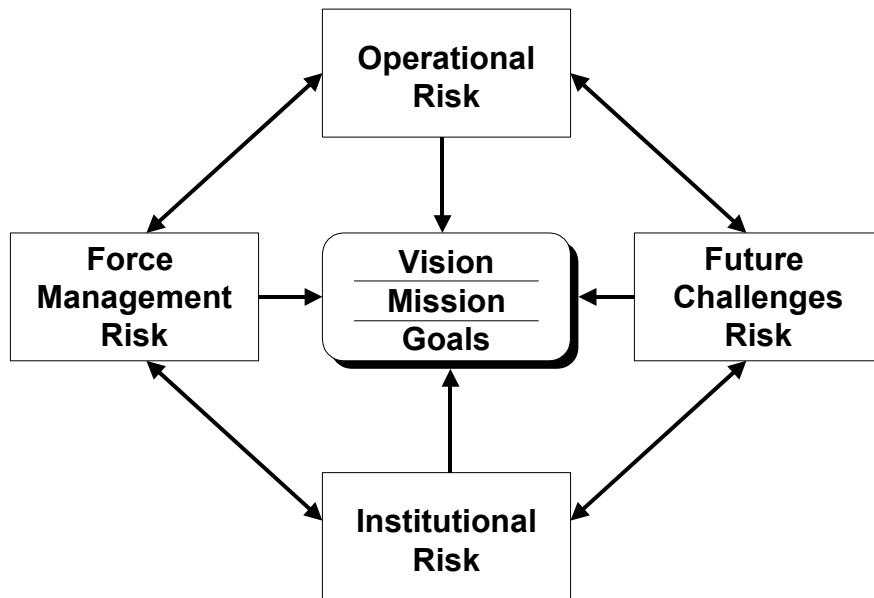


Figure 1. Managed Risk Strategy

- *Force management risk* results from issues affecting the ability to recruit, retain, train, and equip sufficient numbers of quality personnel and sustain the readiness of the force while accomplishing its many operational tasks.
- *Operational risk* stems from factors shaping the ability to achieve military objectives in a near-term conflict or other contingency.

¹ The balanced scorecard concept was introduced by Professor Robert S. Kaplan and Dr. David P. Norton in the *Harvard Business Review* in 1992.

- *Future challenges risk* derives from issues affecting the ability to invest in new capabilities and develop new operational concepts needed to dissuade or defeat mid- to long-term military challenges.
- *Institutional risk* results from factors affecting the ability to develop management practices, processes, metrics, and controls that use resources efficiently and promote the effective operation of the Defense establishment.

In FY06, the Department of Defense increased the total investment in the CBDP. The increased investment is focused on reducing the future challenges risk by increasing resources for the science and technology base as well as the test and evaluation and laboratory infrastructure. The FY06 investment and plans are described in the DoD CBDP Annual Report to Congress. This performance plan focuses on the overall program performance of the most recently completed fiscal year.

1.1 OVERVIEW OF THE DOD CBDP PERFORMANCE PLAN

The DoD has adopted the balanced scorecard concept to provide a managed risk strategy for the CBDP. Since its establishment in 1994 following Congressional passage of the FY94 National Defense Authorization Act (50 U.S. Code, Section 1522), the CBDP has integrated research, development and acquisition (RDA) funds into defense-wide accounts that are overseen by a single office within the Office of the Secretary of Defense.

The DoD CBDP has prepared this performance plan to align itself more closely with the tenets of the Government Performance and Results Act (GPRA). Specifically, the plan:

- Establishes explicit and outcome-oriented goals linked to warfighters' ability to survive, fight, and win in a CBDP environment;
- Identifies quantitative and/or qualitative performance measures that can be used to assess progress towards goal achievement;
- Describes how performance data is validated;
- Describes how RDT&E activities of participating DoD and non-DoD organizations are coordinated to achieve program goals; and
- Identifies human capital, financial, and resource challenges or external factors that limit the ability of the program to achieve its goals.

The major portions of this performance plan link performance goals with performance measurements in terms of those systems and programs, which support the warfighter requirements and goals.

Section 1 provides the vision, mission, goals and performance measures for the CBDP. This section also provides a summary of key performance measures.

Section 2 analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems in support of *Corporate Goal 1*. (See Figure 4 below for summary of DoD CBDP Corporate Goals.) This section focuses on programs that support core warfighter operational goals.

Section 3 analyzes the science and technology base of the program to include basic and applied research and advanced technology development, which support essential capabilities meeting warfighter requirements in support of *Corporate Goal 2*.

Section 4 analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems in support of Corporate Goal 1. In contrast to Section 2, Section 4 focuses on programs related to antiterrorism, force protection, installation protection, and homeland security support activities.

Section 5 analyzes management practices in support of *Corporate Goal 3*: Oversee DoD CB defense modeling and simulation efforts and *Corporate Goal 4*: Improve DoD CB defense management practices – become a high performance organization. Performance goals, which support each corporate level goal of the CBDP, establish a measurable path to incremental achievement of specific goals. These performance goals are supported and evaluated by measurable outputs, which are assessed using performance measures. Performance measures quantify the output of the CBDP for key measures associated with providing a ready force, capable of conducting operations in CB contaminated environments.

1.2 VISION, MISSION, AND VALUES OF THE CBDP

Combat weapons of mass destruction through a strong chemical and biological defense program.

Figure 2. Chemical and Biological Defense Program Vision

This vision statement provides focus and direction to chemical and biological defense research, development, and acquisition efforts. While the principal focus of the CBDP vision is on threats to the warfighter, the vision recognizes the increasing role and importance that DoD personnel and assets will play in support of missions that have not been the traditional domain of the military, namely, DoD support to homeland security. A key aspect of DoD's role in homeland security is a recognition that DoD will support and rely on other federal agencies, as well as state and local emergency responders and private organizations in response to terrorist and others threats to the U.S. homeland.

The *Department of Defense Annual Report to the President and the Congress, 2002*, outlines the paradigm shift in force planning that resulted from changes outlined in the *Quadrennial Defense Review*, September 2001. Requirements are based on supporting the “1-4-2-1” Force Planning Construct.

This force planning construct calls on DoD to maintain regionally tailored forces forward deployed and stationed in *four (4)* critical regions to assure allies, counter coercion and deter aggression against the United States, its allies, and its friends. U.S. forces will remain capable of undertaking major combat operations (MCOs) on a global basis and will train to be effective across a wide range of combat conditions and geographic settings. For planning purposes, U.S. forces will remain capable of rapidly transitioning from its steady-state condition to conducting of an effects-based campaign that aims at swiftly defeating attacks against U.S. allies and friends in any *two (2)* theaters of operation in overlapping timeframes. U.S. forces will retain the capability to decisively defeat an adversary in *one (1)* of the two theaters in which U.S. forces are conducting major combat operations, including the ability to occupy territory or set the conditions for a regime change if so directed by the President. In addition, the new planning approach requires the United States to maintain and prepare its forces for smaller-scale contingency operations in peacetime, preferably in concert with allies and friends.

Provide chemical and biological defense capabilities to effectively execute the National Strategy for Combating Weapons of Mass Destruction. Ensure all capabilities are integrated and coordinated through the Interagency.

Figure 3. Chemical and Biological Defense Program Mission

To support the 1-4-2-1 force-sizing construct and to implement to program vision, **Figure 3** defines the mission for the CBDP. Over the next year, the Department will review this mission and the supporting operational goals to address its evolving role in combating terrorism and homeland security.

A key element in providing a means to establish progress in fulfilling the program mission is the definition of corporate goals for the CBDP, as shown in **Figure 4**. Corporate goals provide the broad warfighter requirements for CB defense operations. These operational goals provide direction for the development, acquisition, and fielding of CB defense equipment. The CBDP thus develops, acquires, and fields equipment that meets warfighter requirements while reducing acquisition costs and time of development. Figure 4 defines the corporate operational goals (and provides a summary of the key materiel capabilities that support these goals.)

- **Goal 1:** Develop Chemical and Biological defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule.
- **Goal 2:** Develop and support a science and technology base program that integrates the DoD and other Federal Agency chemical and biological defense research efforts.
- **Goal 3:** Oversee DoD chemical and biological defense modeling and simulation efforts.
- **Goal 4:** Improve DoD chemical and biological defense management practices – become a high performance organization.

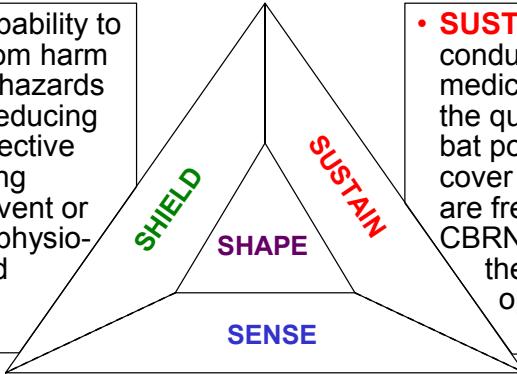
Figure 4. Chemical and Biological Defense Program Corporate Goals

1.3 Joint Chemical and Biological Defense Functional Concepts and Operational Goals

In July 2003, the JRO-CBRN Defense completed a CBRN Defense Baseline Capabilities Assessment. Prior assessments focused on systems rather than on capabilities. In order to validate the process, the initial baseline assessment focused on the traditional warfighter mission, or passive defense capabilities. Future assessments will establish a baseline for all DoD CBRN defense missions, including force protection, consequence management, and homeland security, while updating the assessment of passive defense capabilities. In addition, the baseline capability assessment establishes an integrated joint functional concept that supersedes the concepts of Avoid, Protect, and Decontaminate that are outlined in Joint Publication 3-11, *Joint Operations in an NBC Environment*. **Figure 5** defines the Joint CBRN defense joint functional concepts—Sense, Shape, Shield, and Sustain. The joint functional concepts represent an integrated network of capabilities to support the warfighter. No single system, technology, or approach is sufficient

- **SHAPE** – Provides the ability to characterize the CBRN hazard to the force commander to develop a clear understanding of the current and predicted CBRN situation; collect, query, and assimilate info from sensors, intelligence, medical, etc., in near real time to inform personnel, provide actual and potential impacts of CBRN hazards; envision critical SENSE, SHIELD and SUSTAIN end states (preparation for operations); visualize the sequence of events that moves the force from its current state to those end states.

- **SHIELD** – The capability to shield the force from harm caused by CBRN hazards by preventing or reducing individual and collective exposures, applying prophylaxis to prevent or mitigate negative physiological effects, and protecting critical equipment



- **SUSTAIN** – The ability to conduct decontamination and medical actions that enable the quick restoration of combat power, maintain and recover essential functions that are free from the effects of CBRN hazards, and facilitate the return to pre-incident operational capability as soon as possible.

- **SENSE** – The capability to continually provide the information about the CBRN situation at a time and place by detecting, identifying, and quantifying CBRN hazards in air, water, on land, on personnel, equipment or facilities. This capability includes detecting, identifying, and quantifying those CBRN hazards in all physical states (solid, liquid, gas).

Figure 5. Joint CBRN Defense Joint Functional Concepts (*Sense, Shape, Shield, Sustain*)

to defend against the spectrum of CBRN agents, delivery systems, and adversaries, which may use these weapons to counter U.S. superiority in conventional forces.

Figure 6 identifies CBRN defense operational goals. Each operational goal is directly associated with one of the Joint Functional Concepts. In turn, specific projects and programs within advanced development and procurement are associated with one or more of the operational goals. Section 2 of this plan provides the assessment of these programs and the status of their progress in supporting operational goals.

Sense	Shape	Shield	Sustain
1. Point Detection (Chemical, Biological, and Radiological)	4. Integrated Early Warning	7. Respiratory and Ocular Protection	11. Individual Decontamination
2. Stand-off Detection	5. Battlespace Management	8. Percutaneous Protection	12. Equipment Decontamination
3. NBC Reconnaissance (Chemical, Biological, and Radiological)	6. Battlespace Analysis	9. Expeditionary Collective Protection	13. Fixed Site Decontamination
		10. Medical Prophylaxes	14. Medical Diagnostics
			15. Medical Therapeutics

Figure 6. CBRN Defense Operational Goals

1.4 PERFORMANCE PLAN METHODOLOGY

1.4.1 Data Identification and Analysis

The performance plan draws on information and consolidates data from several sources, including:

- DoD CBDP Modernization Plan,
- DoD CBDP Research, Development, and Acquisition (RDA) Plan,
- DoD CBDP Logistics Support Plan,
- The Joint Warfighting Science and Technology Plan,
- The Defense Technology Area Plan,
- The Chemical and Biological Defense (CBD) Technology Area Review and Assessment (TARA),
- JRO-CBRND Annual CBRN Defense Baseline Capabilities Assessment
- The DoD CBDP Annual Report to Congress,
- President's Budget Submissions for the DoD CB Defense Program.

In addition, the performance plan draws on current data contained in documents prepared in support of the PPBS, including Defense Planning Guidance, the CBDP Program Strategy Guidance, the Program Objectives Memorandum, the President's Budget and supporting detailed information in the RDT&E and Procurement Congressional Justification Books.

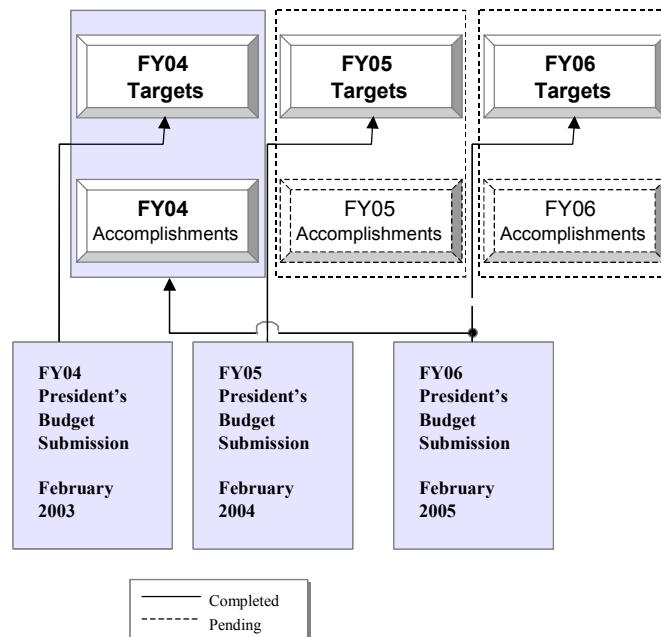


Figure 7. Performance Plan Methodology

To measure performance within the overall CBDP, individual programs are assessed to determine how each actually performed in comparison to the stated program targets. The specific targets represent the program objectives for each year. **Figure 7** illustrates the sources of information that allow a comparison over time. As illustrated, the *targets* for each fiscal year (FY) are derived for that year's corresponding President's Budget submission to Congress. The accomplishments are reported in the President's Budget immediately following the completion

of that fiscal year. Thus, the FY06 President's Budget Submission includes FY04 Accomplishments. FY05 and FY06 targets are derived from their respective budget submissions.

This methodology provides a means of ensuring accurate data reporting. Where targets are met, this is stated as "targets met" rather than repeating the targets. Where program accomplishments may be at variance with program targets, the differences are explained. Variances do not necessarily mean poor performance. Variances may occur as a result of schedule changes in supporting programs, changes in funding, or unexpected test results.

When changes are made to a program after the budget is submitted, changes are explained following the completion of that fiscal year. This allows for a fair comparison by providing a detailed description of accomplishments and the variance from the targets. Targets are not changed to reflect accomplishments. Thus, for example, funds added to the FY04 budget above the President's Budget Request result in changes to the FY04 targets. However, since these changes occurred after the FY04 President's Budget was submitted, the additional resources and targets will be explained in the FY04 accomplishments.

1.4.2 Performance Analysis

Analysis of program data is only part of the assessment process. The next step in the assessment is a comparison of the results of the data analysis against performance goals, operational goals, corporate goals, and the overall CDP mission. Following are several assumptions and criteria that guide the assessment of programs.

- Operational goals are driven by and derived from Joint Functional Concepts, hence the mission, goals, and operational concepts drive program development.
- Operational goals are *supported* by programs, rather than *driven* by programs.
- All funded programs should support an operational goal. (The only exception is for supporting technologies, which are necessary for the development or execution of a program.)
- A program may support more than one operational goal.
- Multiple programs supporting the same operational goal can be evaluated to determine complementarities, synergies, or redundancies.
- Not all operational goals may be supported by a program. This may be the result of the development of a new mission or operational goal, or from the lack of an available technology.
- Programs that do not support an operational goal may not be demonstrated to support the program mission and may reflect an inappropriate use of resources.

1.4.3 Advanced Development and Acquisition Performance Goals and Measures

The following sections provide near-term performance goals, performance measures, and targets that support program corporate level goals. For the purpose of this strategy plan, FY04 is the current assessment year, for which actual performance can be assessed; FY05 and FY06 are the future assessment years for which targets are established, and will be assessed in future annual performance plans. Future material solutions refer to those that will be addressed during years cited, some of which may be in the technology base.

1.4.3.1 Metric Description. Research, Development and Acquisition (RDA) programs within the DoD CDP aim to ensure that U.S. forces are provided with the best equipment, which will ensure survivability and mission accomplishment on any future battlefield where chemical or

biological agents are employed. The increased complexity of modern warfare demands that CB defense equipment be fielded in the most cost effective and expeditious manner possible. Additionally, the evolving threat environment requires a capabilities-based approach, which requires identifying capabilities that U.S. military forces will need to defend against adversaries since specific adversary's intentions may not be possible to determine. Specific materiel solutions are identified which support numerous Combatant Command requirements. Each materiel solution's progress is measured by monitoring specific performance goals and targets in the planning years. Each of these metrics supports the ultimate objective; that of fielding new and improved CB defense equipment to our warfighting forces.

1.4.3.2 Verification and Validation (V&V) of Metrics. V&V is accomplished through a number of processes. First and foremost, the Planning, Programming, Budget and Execution (PPBE) system is the key process employed by the DoD CBDP to ensure program performance goals and targets are implemented into the budget. Through the PPBE system, the program apportions resources annually in support of the goals articulated in the planning process.

The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense Programs, DATSD (CBD), issues detailed planning guidance in the DoD CBDP Program Strategy Guidance, which is used in formulating and preparing the Program Objective Memorandum (POM). This document serves as a strategic planning document, and provides a framework for assessment of the POM and how well it meets stated goals and targets. In conjunction with the publication of the POM, the JRO-CBRND develops an assessment of how well the goals are met. The OSD staff in turn assesses these goals, as the POM is reviewed and adjusted through a review process, culminating in the finalization of the President's Budget for the DoD CBDP. The PPBE process is an effective mechanism for the DATSD (CBD) to match operational CBRN defense goals and targets with the appropriate budgetary resources in a fiscally constrained environment.

In addition to the annual PPBE process, the DoD CBDP relies on an oversight process, which permits reviews of program status on a monthly basis through staff review of Joint Service Chemical-Biological Information System (JSCBIS) information sheets. System Program Managers (PMs) and item managers prepare quarterly system summary sheets, which are reviewed by the OSD staff.

Another V&V mechanism used by the CBDP is the Annual Report to Congress. During preparation of the report, the CB defense community reports annual progress within the various facets of the program. Annual accomplishment and plans for the future, as well as issues and factors that limit the ability of the program to achieve its goals, are documented and summarized along with the President's Budget.

For the performance metrics related to the Joint Functional Concepts (see Section 1.5), these are developed through an annual assessment process conducted by the JRO-CBRN Defense. The Joint Requirements Oversight Council (JROC) provides approval and validation of the results annually.

1.5 SUMMARY OF KEY PERFORMANCE METRICS

1.5.1 Measuring Progress Towards Operational Goals (*Operational Risk*)

Following the JROC approved Baseline Capability Assessment of July 2003, **Figures 7a-d** illustrates the assessment of core warfighting capabilities and provides a measure of how each operational goal is progressing as well as each overall joint functional concept. Each operational goal is measured on a relative scale of 0–10 with “10” representing fielding of objective capabilities. This assessment will be expanded in the future to include additional warfighting mission, specifically including consequence management, force protection, installation protection, and homeland security support activities. The baseline assessment provides a summary evaluation of what capability levels U.S. forces have today and what capabilities are anticipated in the future. These assessments assumed planned schedules will be achieved and threshold key performance parameters (KPPs) will be met for all systems. The FY06 President’s Budget Submission was structured during the Enhanced Planning Process to address overall capability limitations identified in the following figures.

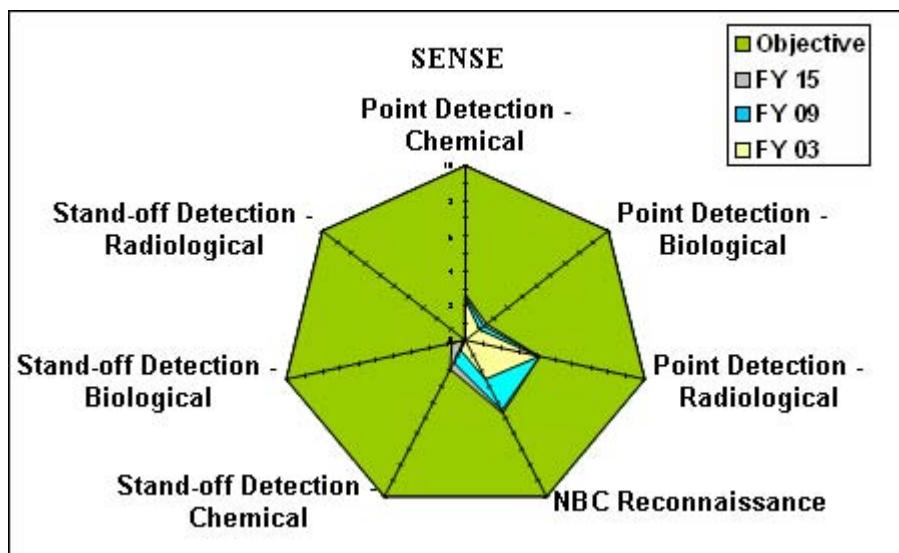


Figure 7a. CBRN Defense Summary Assessment of Core Capabilities – SENSE

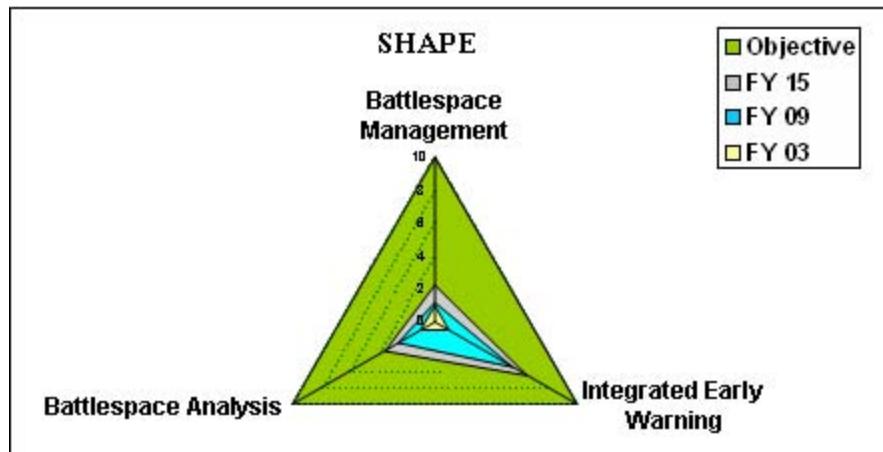


Figure 7b. CBRN Defense Summary Assessment of Core Capabilities – SHAPE

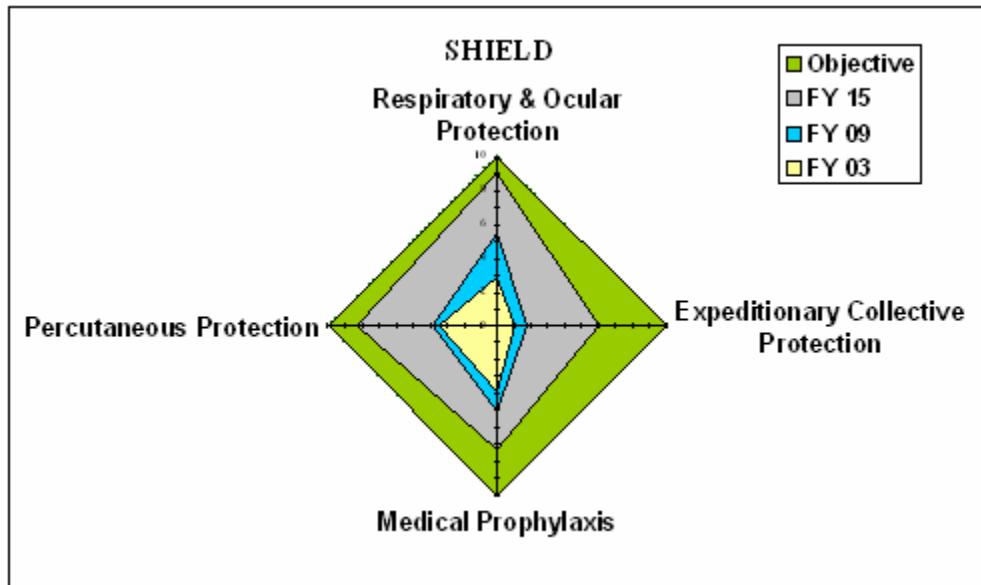


Figure 7c. CBRN Defense Summary Assessment of Core Capabilities – SHIELD

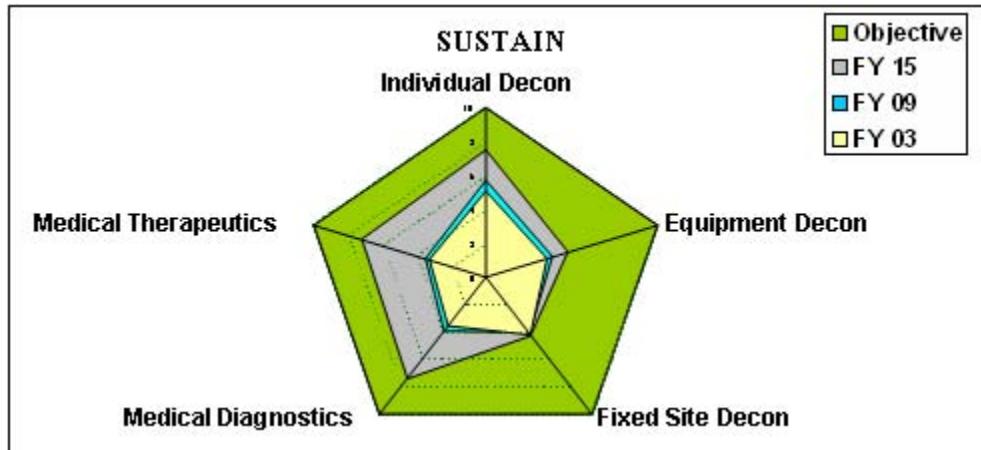


Figure 7d. CBRN Defense Summary Assessment of Core Capabilities – SUSTAIN

1.5.2 Developing and Deploying Transformational Capabilities (*Future Challenges Risk*)

This section provides a summary of key activities in (1) advanced development, and (2) the science and technology base. Oversight of the CBDP is tailored by creating an “index of systems” to measure performance of CBDP functional areas based on the criticality, complexity and cost of individual CBDP programs. These index systems are referred to as “Sentinel” systems. A Sentinel system is a program in advanced development that represents a balance of cost, complexity, and criticality as an indicator of the general programmatic health of the functional area. The standard exit criteria for a program selected as a Sentinel system will be successful Full Rate Production Decision Review by the Defense Acquisition Executive (DAE).

The current Sentinel CBDP systems include:

- Joint Warning and Reporting Network (JWARN),
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLS CAD),
- Joint Service Lightweight Nuclear, Biological, Chemical Reconnaissance System (JSLNCRS),
- Joint Chemical Agent Detector (JCAD), and
- Joint Biological Point Detection System (JB PDS).

Figure 8 illustrates the planned acquisition cycle time for the Sentinel systems. **Figure 9** provides the specific dates. The target acquisition time has been established by DoD for Major Defense Acquisition Programs. This same target is used for comparison by the CBDP for its sentinel systems.

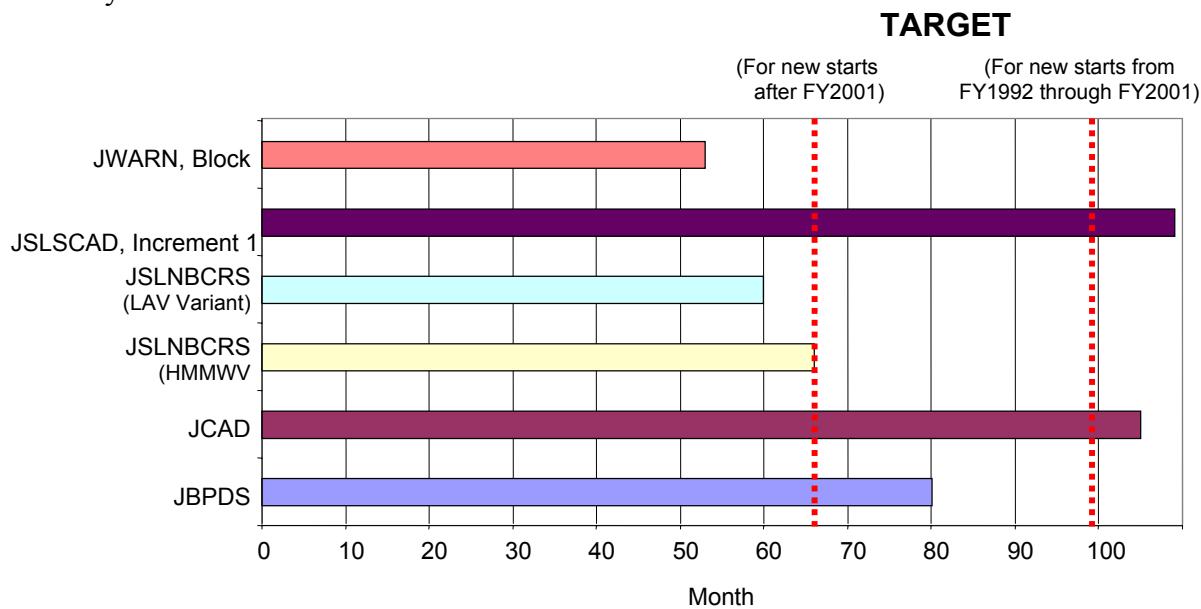


Figure 8. Acquisition Cycle Time for CBDP Sentinel Systems

System	Milestone B (Program Initiation)	Program Fielding	Duration (months)
JBPDS	Jun-97	Feb-04	80
JCAD	Dec-97	Sep-06	105
JSLNBCRS (HMMWV)	Jun-01	Dec-06	66
JSLNBCRS (LAV)	Jun-01	Jun-06	60
JSLSCAD, Increment 1	Sep-96	Oct-05	109
JWARN, Block II	Jul-03	Dec-07	53
TARGET (For new starts from FY1992 through FY2001)			99
TARGET (For new starts after FY2001)			66

Notes:

- [1] "Program Initiation" is defined as the date of Milestone B approval
- [2] "Program Fielding" is defined as "Initial Operational Capability" (IOC) or "First Unit Equipped" (FUE)
- [3] Dates shown are projected threshold planning dates (or actual dates if applicable).
- [4] Duration times are rounded.

Figure 9. Acquisition Cycle Time for CBDP Sentinel Systems

For science and technology programs, **Figure 10** provides a summary of Defense Technology Objectives (DTOs), which represent key high priority projects within the science and technology base. A complete assessment of the science and technology programs is provided in Section 3.0 of this plan.

	FY04		FY05	FY06
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	70*	80	80
Total Number of DTOs	28 of 35	19 of 27*		

* Seven CBD DTOs were rated as yellow [Y] and one as red [R]. Eight were not rated because they were either cancelled or completed in FY03 or FY04. While below the goal, the rating of 70% is up from 58% in FY03.

Figure 10. Status of DTOs as rated by the Chemical and Biological Defense Technology Area Review and Assessment

1.5.3 Logistics and Training Capabilities (*Force Management Risk*)

Critical chemical and biological defense capabilities for the warfighter are provided through the operations and sustainment (O&S) accounts of the Military Departments in addition to the RDA funds of the CBDP. *Logistics Risks Assessments* are provided in Chapter 3 of the DoD CBDP Annual Report to Congress and provides information on capabilities in stock and available to the warfighter at the end of FY04 and planned for future years.

Data on personnel training and education is provided in Chapter 4 of the DoD CBDP Annual Report to Congress. Examples of the metrics for training include the following:

- Summary of Army Medical Department (AMEDD) CBRN Training
- U.S. Army Professional and Initial Entry Training
- U.S. Army Specialized Professional Training
- Total AMEDD Personnel Trained
- Major Accident and WMD In-Residence Training Requirements
- Air Force Professional Training

- Air Force Medical Service (AFMS) Medical Management of Biological and Chemical Casualties—Training for Providers
- AFMS CBRNE Training for Deployable Personnel
- Navy Medical CBRN Defense Training Status

Additional information on exercises, training standards, and related chemical and biological defense training activities is also detailed.

1.5.4 Improving Management Practices (*Institutional Risk*)

Managing institutional risk results from factors affecting the ability to develop management practices, processes, metrics, and controls that use resources efficiently and promote the effective operations. Following are key management activities that are being pursued to manage institutional risk.

Streamlining the decision process — Chapter 1 of the Annual Report of the CBDP describes the management and oversight structure. The most significant changes in the management structure was the program reorganization that was approved on April 22, 2003. This reorganization streamlined the decision process by reducing the number of Milestone Decision Authorities from nine to one. The Milestone Decision Authority (MDA) for the CBDP is the Under Secretary of Defense for Acquisition, Technology and Logistics, USD (AT&L). The USD (AT&L) has delegated MDA responsibilities (except for selected systems) to Army Acquisition Executive, who has further delegated MDA responsibilities to the Joint Program Executive Officer for Chemical and Biological Defense.

Program Balance — Annex H of the Annual Report of the CBDP provides information on RDA funding. DoD annually reviews the program budget to ensure that program activities are balanced among science & technology, advanced development, and procurement to ensure technology transitions as well as to ensure capabilities are being developed to address near, mid, and far term operational needs.

Improving Test & Evaluation Infrastructure — Annex J of the Annual Report of the CBDP provides information on the DoD test and evaluation (T&E) infrastructure. T&E Infrastructure programs were budgeted and submitted as separate needs. In the FY06 President's Budget Submission, budget needs for the T&E infrastructure were integrated with the research, development, and acquisition programs. This budget was based on technology needs and directions, restructured acquisition programs, and integrated the T&E capabilities to execute these programs. The programs were time and funding sequenced to be executable in terms of having the technologies demonstrated and transitioned in synchronization with the T&E capabilities. Thus, the milestones of the acquisition programs were based on the availability of not only the financial resources, but the technology and T&E resources needed to execute the programs. The full effect of this integrated, executable program structure will be realized beginning in FY06.

ADVANCED DEVELOPMENT AND PROCUREMENT PERFORMANCE GOALS AND MEASURES

2.0 OVERVIEW

Advanced development and procurement within the CBDP is a critical means for ensuring that the U.S. military has the capability to operate effectively and decisively in the face of biological or chemical warfare threats at home or abroad. Advanced development and procurement specifically support the U.S. military has the capability to operate effectively and decisively in the face of chemical and biological threats at home or abroad. Advanced development and procurement specifically support **Corporate Goal 1: Develop chemical and biological defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule**. The operational goals—Sense, Shape, Shield, and Sustain—outlined in Section 1.3 above provide the link between the programs described below and the overall mission of the CBDP. The following information is provided for each operational goal in this section:

- A list of current and future materiel solutions,
- Procurement data, including:
 - (1) an assessment of procurement targets *vs.* actual accomplishments for FY04, and
 - (2) procurement targets for FY05 and FY06.
- RDT&E data, including:
 - (1) an assessment of RDT&E targets *vs.* actual accomplishments for FY04, and
 - (2) RDT&E targets for FY05 and FY06.
- An overall assessment for activities supporting each operational goal.

2.1 OPERATIONAL GOAL 1: SENSE

2.1.1 Performance Goal 1.1 – Point Detection (Chemical, Biological, and Radiological)

Current Materiel Solutions	Future Materiel Solutions
Chemical Point Detection	
M8A1 Chemical Agent Alarm (Legacy) M22 ACADA Improved (CA) Point Detection System (IPDS) M8 paper (Service O&M responsibility) M9 paper (Service O&M responsibility) M256A1 Detector Kit (Service O&M responsibility) Chemical Agent Monitor (CAM) (Legacy system) Improved CAM (ICAM) M272A1 Water Test Kit (Service O&M responsibility)	Joint Chemical Agent Detector (JCAD) Joint CB Agent Water Monitor (JCBAWM) Joint Contaminated Surface Detector (JCSD)
Biological Point Detection	
Joint Portal Shield Biological Integrated Detection System (BIDS) DoD Biological Sampling Kit Interim Biological Agent Detector System (IBADS) Critical Reagents Program (CRP)	Joint Biological Point Detection System (JBPDPS) Joint Biological Tactical detection System (JBTDs) Situational Awareness and Response Network (STARNET) ACTD

Current Materiel Solutions	Future Materiel Solutions
Radiological Point Detection	
- AN/UDR-13 Pocket Radiac - AN/PDR-75 Radiac - AN/PDR-77 Radiac - AN/VDR-2 Radiac - Multi-Function Radiac - ADM-300A	n/a

2.1.2 Materiel Solutions Performance Measurements – **Point Detection (Chemical, Biological, and Radiological)**

2.1.2.1 Current Procurement Targets – Point Detection (Chemical)

System	FY04		FY05	FY06
	Target	Actual	Target	Target
ACADA		3,028	4,895	266
ICAM			686	
JCAD	588	0	0	526

2.1.2.2 Current R&D Targets – JCAD

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - JCAD - Complete hardware and software development. - JCAD - Initiate government evaluation of commercial detectors. - JCAD - Purchase commercial off-the-shelf (COTS) systems and support (up to 105 systems at \$26K each). - JCAD - Continue systems engineering support. 	<ul style="list-style-type: none"> - JCAD - Completed EMD hardware and software development. - JCAD - Initiated government evaluation of commercial detectors to include production qualification testing (PQT) and chamber design and validation. - JCAD - Purchased commercial systems and support (20 systems each from four vendors; 80 systems total. 20 systems at \$8,875 each from vendor one; 20 systems at \$25,535 each from vendor two; 20 systems at \$12,827 each from vendor three; and 20 systems at \$12,743 each from vendor four.) (Increment 1). - JCAD - Initiated systems engineering support for commercial detector program.

2.1.2.3 Future R&D Targets – JCAD

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - N/A (Funding cancelled in FY05) 	<ul style="list-style-type: none"> - JCAD - Provide contract support of commercial test systems. - JCAD - Conduct government evaluation of commercial detector. Efforts include completing PQT, performing MOT&E, and preparing test methodology for Increment 2 low-level detection requirements. - JCAD - Provide systems engineering support. - JCAD - Purchase Increment 2 systems and support (120 systems at \$13.5K each. Vendor TBS). - JCAD - (T&E Capability) - Design agent simulant dissemination systems, sampling systems, monitoring systems, and establishment of testing, safety and security protocols.

2.1.2.4 Current Procurement Targets – Joint CB Agent Water Monitor (JCBAWM)

System	FY04		FY05	FY06
	Target	Actual	Target	Target
JCBAWM			24020	

2.1.2.5 Current R&D Targets – JCBAWM

FY 2004 Targets	Actual Performance
- n/a	- n/a

2.1.2.6 Future R&D Targets – JCBAWM

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JCBAWM - Initiate purchase of test items (24,000 test tickets at \$0.1K each, \$2.4M total; and 20 ticket readers at \$1K each, \$20K total. Vendors: TBS). - JCBAWM - Establish Program Office and initiate test and evaluation efforts to include preparation of test methodology, design of test set-up and development of equipment specifications. - JCBAWM - Initiate systems engineering support. 	<ul style="list-style-type: none"> - JCBAWM - Continue test and evaluation efforts. Initiate probability studies. - JCBAWM - Continue systems engineering support. - JCBAWM - Initiate test and evaluation efforts to include developing test methodology for bio warfare agents. - JCBAWM - Initiate systems engineering support (Government).

2.1.2.7 Current Procurement Targets – Joint Contaminated Surface Detector (JCSD)

2.1.2.8 Current R&D Targets – JCSD

FY 2004 Targets	Actual Performance
- n/a	<ul style="list-style-type: none"> - JCSD - Completed systems engineering and design, and continued logistics support planning. Built first prototype unit (\$500K), and ordered parts for two additional units for laboratory and field testing to support transition to NBC Reconnaissance P3I program. - JCSD - Continued sensor performance and qualification testing. Initiated modifications to vehicle platform, integrated system in vehicle, and conducted dust/smoke effects testing as well as customer demonstration. - JCSD - Initiated CB Warfare Agent Detector Chip development efforts. - JCSD - Initiated Handheld Biological Agent Identifier development efforts.

2.1.2.9 Future R&D Targets – JCSD

FY 2005 Targets	FY 2006 Targets
- N/A	- N/A

2.1.2.10 Current Procurement Targets – Joint Biological Point Detection System (JBPDs)

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JBPDs	111	111	133	113

2.1.2.11 Current R&D Targets – JBPDS

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - JBPDS BLK I - Complete advanced Biological Aerosol Warning System (BAWS) upgrade 	<ul style="list-style-type: none"> - JBPDS BLK I - All targets metplus provided systems engineering support. - JBPDS BLK II - Conducted feasibility study for current and near-future

FY 2004 Targets	Actual Performance
<p>for Low Rate Initial Production (LRIP) systems to meet Joint Operational Requirements Document (JORD) objective requirements for detection.</p> <ul style="list-style-type: none"> - JBPDS BLK I - Complete Multi-Service Operational Test and Evaluation (MOT&E) for the Army, Navy, and Air Force (Phases II-V). Provide final System Evaluation Report (SER). 	<p>biological point detection systems.</p> <ul style="list-style-type: none"> - JBPDS BLK II - Conducted study to examine the additional value obtained through Whole System Live Agent Testing - JBPDS BLK II - Performed CB sensor and overarching technology architecture analyses with resultant models to provide cost benefit trade offs associated with the transition of technologies to guide future investments. Evaluated new concepts that would allow the use of emerging technologies for early warning and point detection within the architectural framework. that would allow the use of emerging technologies for early warning and point detection within the architectural framework. (WSLAT) on biological point detection systems. - JBPDS BLK II - Conducted methodology work in support of WSLAT testing. - JBPDS BLK II - Conducted initial modeling and simulation efforts in support of WSLAT testing. - JBPDS BLK II - Provided government engineering, program management, and technical support of WSLAT testing.

2.1.2.12 Future R&D Targets – JBPDS

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JBPDS - Purchase JBPDS test hardware, Man Portable, XM 96 systems (5 @ \$503K ea.) and one (1) System Support Package (\$350K) for Whole System Live Agent Test (WSLAT) support. - JBPDS - Initiate and select spiral improvements for the JBPDS LRUs to meet objective requirement for number of agents and sensitivity. - JBPDS - Adapt the Array Bio Sensor as an upgrade to the JBPDS. - JBPDS - Provide systems engineering support 	<ul style="list-style-type: none"> - JBPDS - Initiate, select, and validate improved collector. - JBPDS - Initiate, develop, and validate embedded training. - JBPDS - Support Whole System Live Agent Test (WSLAT) execution. - JBPDS - Purchase one JBPDS System Support Package (\$350K), for support to WSLAT - JPBDS (T&E Capability) - Prepare preliminary chamber design - JPBDS - Provide system engineering support. - JPBDS - (T&E Capability) - Initiate designs and prepare statements of work and deliverables for contractors. Provide chamber and fixtures, specify instrumentation and control systems.

2.1.2.13 Current Procurement Targets – Interim Biological Agent Detector System (IBADS)

System	FY04		FY05	FY06
	Target	Actual	Target	Target
IBADS		(-4)	(-9)	

2.1.2.14 Current R&D Targets – IBADS

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - The IBADS is currently being decommissioned and will be replaced by the JBPDS in FY05 	<ul style="list-style-type: none"> - IBADS - Continued to provide engineering and technical support to maintain fielded systems. The Navy decommissioned four (4) IBADS.

2.1.2.15 Future R&D Targets – IBADS

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - IBADS - Complete the decommissioning of the remaining nine (9) shipboard IBADS. 	<ul style="list-style-type: none"> -

2.1.2.16 Current Procurement Targets – Critical Reagents Program (CRP)

System	FY04		FY05	FY06
	Target	Actual	Target	Target
CRP		88	82	82

2.1.2.17 Current R&D Targets – Critical Reagent Program (CRP)

FY 2004 Targets	Actual Performance
- N/A	<ul style="list-style-type: none"> - Completed insertion of International Task Force (ITF)-6A agents into polymerase chain reaction (PCR) and electrochemiluminescence (ECL) formats - Continued antibody development of ITF-6B targets. - Continued expansion of select agent reference material, validation of assays, and scale up of select agent reference material. - Developed and instituted automation technology solutions to improve processes and operations of the clinical laboratory.

2.1.2.18 Future R&D Targets – Critical Reagent Program (CRP)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Continue antibody development of ITF-6B targets. - Continue expansion of select agent reference material, validation of assays, and scale up of select agent reference material. - Initiate development of PCR and ECL assays to ITF-6B. 	<ul style="list-style-type: none"> - Complete development of PCR and ECL assays, and antibodies to ITF-6B. - Continue expansion of select agent reference material, validation of assays, and scale up of select agent reference material. Initiate expansion of unified cell culture collection (UCC). - Initiate and complete a formal Quality Assurance/Quality Control (QA/QC), validation, Developmental Testing (DT), and Operational Testing (OT) program to encompass the transition and fielding of biological detection assays.

2.1.3 Performance Goal 1.2 – Standoff Detection (Chemical, Biological, and Radiological)

Current Materiel Solutions	Future Materiel Solutions
Chemical Standoff Detection	
M21 Remote Sensing Chemical Agent Alarm (RSICAL) (Legacy System) AN/KAS-1, Chemical Warfare Directional Detector (Legacy System)	Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) Mobile Chemical Agent Detector (MCAD)
Biological Standoff Detection	
	Joint Biological Standoff Detection System (JBSDS)
Radiological Standoff Detection	
None	none

2.1.4 Materiel Solutions Performance Measurements – Standoff Detection (Chemical, Biological, and Radiological)

2.1.4.1 Current Procurement Targets – Standoff Detection (Chemical + Biological)

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JSLSCAD	121	27	4	42
JBSDS		6		18
MCAD		6		

2.1.4.2 Current R&D Targets – JSLSCAD

FY 2004 Targets	Actual Performance
- Initiate support of the Stryker Nuclear Biological	<ul style="list-style-type: none"> - All targets met plus initiated modeling and

FY 2004 Targets	Actual Performance
<p>Reconnaissance Vehicle (NBCRV) Production Qualification Test and Limited User Test (LUT).</p> <ul style="list-style-type: none"> - Initiate methodology development to support the comparison of commercially available remote sensing detectors. - Choose and purchase candidate remote sensing detectors for testing. - Initiate and conduct testing of remote detectors to support National Research Council (NRC) findings. 	simulation efforts to allow evaluation of standoff detectors under various challenge environments and provided government systems engineering support..

2.1.4.3 Future R&D Targets – JSLS CAD

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Continue Increment 1 evaluation to support NRC findings (M&S) and initiate Increment 2 evaluation efforts. - Initiate evaluation of candidate commercial remote detection systems (Increment 2). - Procure additional Increment 2 test items and support (three detectors at \$387K each from vendor one; three detectors at \$300K each from vendor two; and three detectors at \$484K each from vendor three for a total of 9 detectors) - Integrate commercial systems into platforms. - Support remote sensing test facility design and use for testing of commercial detectors. - Continue to provide government systems engineering support. 	<ul style="list-style-type: none"> - Continue evaluation of commercial remote detection systems and downselect to a single system (Increment 2). - Initiate and plan for operational test and evaluation of selected commercial system. - Continue testing and analysis to support NRC findings and refine modeling techniques. - Continue integration and support of the commercial remote detection system onto various platforms. - Initiate Increment 3 technology assessment. - Initiate product improvement program for Increment 1 detection software. - Continue to provide government systems engineering support. - (T&E Capability) Initiate data gathering efforts from various battle-space representative environments to include correlating and archiving spectral background signatures from these environments. - (T&E Capability) Coordinate/facilitate subject matter expert support. - (T&E Capability) Initiate purchase of data collection instrumentation.

2.1.4.4 Current R&D Targets –Artemis

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue update of Milestone B program documentation. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis. - Continue update of system architecture, system specification and risk mitigation plan through a Joint SE IPT. - Continue test strategy and test methodology development to include stimulant to real agent correlation, stimulant and test range selection, aerosol and liquid spectra collection. Update TEMP through a Joint T&E IPT. - Continue risk reduction efforts to further reduce overall program risk in support of the development of key components of an active - Emitter multi-wave LIDAR technology. Key components considered high risk are solid state lasers, non-consumable detectors, and advances detection algorithms. 	<ul style="list-style-type: none"> - All targets met.

FY 2004 Targets	Actual Performance
<p>Demonstrate and validate performance of these components.</p> <ul style="list-style-type: none"> - Continue support for the development of standoff detection test infrastructure to provide the capability to adequately test the ARTEMIS system. Develop an active standoff chamber fixture for testing the ARTEMIS system against chemical warfare simulants. Develop precise referee systems to support evaluation of the ARTEMIS system in an open air simulant test. 	

2.1.4.5 Future R&D Targets –Artemis

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Perform program close out and archive the products such as Component Advanced Development Reports, Liquid Agent Spectra Measurements, LIDAR Performance Model, Spectral Algorithm Stimulator Report and Simulant Selection Analysis. Develop reports of major program decisions and lessons learned. Coordinate with DTRA to establish Technology Readiness Level of Frequency Agile LIDAR components. Perform financial management, scheduling, planning and reporting. - Complete system performance modeling activities to evaluate LIDAR performance against the full range of threat agents and to ambient water density and ozone. Tailor the performance analyses to support the on going Standoff Chemical Detection Analysis being led by MIT Lincoln Laboratory. Included will be performance analysis efforts to support an Analysis of Alternatives (AoA) update to the July 2001 AoA. The performance analysis products will assist JPEO-CBD in crafting a technical and acquisition way ahead for standoff chemical detection of vapors, aerosols and rains. - Update the July 2001 Analysis of Alternatives. Collect information from Industry, Academia, and Government agencies to develop an AoA for Standoff Chemical Detection. Integrate the products of the MIT Standoff Chemical Detection Analysis and associated DTRA TRL assessments into the AoA. Investigate alternative technology approaches, potential common solutions to general standoff needs, and system size/weight/cost/performance tradeoffs. Include both fixed site and "on the move" requirements as part of the evaluation. 	<ul style="list-style-type: none"> - This program closed out in FY05.

2.1.4.6 Current R&D Targets – JBSDS

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - JBSDS - Initiate planning for Initial Operational Test and Evaluation (IOT&E). - JBSDS - Award development contract to one of two competing candidate systems to enhance performance, develop Integrated Logistic Support (ILS) and documentation (technical manuals, specifications, etc.), and support Low Rate Initial Production (LRIP). - JBSDS - Initiate development of next generation JBSDS system. This includes modeling and simulation analysis, market research analysis, and Cost As An Independent Variable (CAIV) analysis - JBSDS - Initiate background testing and analysis at multiple locations to refine detection/discrimination algorithm. - JBSDS - Initiate evaluation of CBMS II Chemical Biological Monitoring System. 	<ul style="list-style-type: none"> - JBSDS - Completed development contract award. - JBSDS - Completed Production Qualification Test (PQT) and analysis. - JBSDS - Initiated background test, planning and analysis at multiple locations to refine detection/discrimination algorithm. - JBSDS - Completed Milestone B and Milestone C activities. - JBSDS - Initiated and completed the prototype upgrade and Engineering Design Test (EDT) planning. - JBSDS - Initiated development of Increment II JBSDS system. This includes modeling and simulation analysis and market research analysis. - JBSDS - Provided systems engineering support.

2.1.4.7 Future R&D Targets – JBSDS

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JBSDS - Continue development contract (including 	<ul style="list-style-type: none"> - JBSDS Increment II - Initiate Milestone B (MS B)

FY 2005 Targets	FY 2006 Targets
<p>contractor support of Production Verification Test (PVT) and Initial Operational Test and Evaluation (IOT&E)).</p> <ul style="list-style-type: none"> - JBSDS - Initiate PVT. - JBSDS - Initiate Multi-Service Operational Test and Evaluation (MOT&E). - JBSDS - Initiate Modeling and Simulation for JBSDS Increment II. - JBSDS - Initiate demonstration of Increment II technologies. - JBSDS - Provide systems engineering support. 	<p>preparations.</p> <ul style="list-style-type: none"> - JBSDS Increment II - Initiate System Development Contract Solicitation. - JBSDS Increment II - Initiate design & development of engineering prototype. - JBSDS Increment II - Initiate Supportability Strategy. - JBSDS Increment II - Initiate Test Methodology Development. - JBSDS Increment II - Provide systems engineering support. - JBSDS Increment II - Initiate agent/simulant correlation.

2.1.4.8 Current R&D Targets – MCAD

FY 2004 Targets	Actual Performance
- n/a	<ul style="list-style-type: none"> - MCAD - Procured six commercial MCADs (\$484K each, \$2,904K total) and associated support for testing. - MCAD - Completed Toxic Industrial Chemical Testing.

2.1.4.9 Future R&D Targets – MCAD

FY 2005 Targets	FY 2006 Targets
- n/a	- n/a

2.1.5 Performance Goal 1.3 – NBC Reconnaissance (Chemical, Biological, and Radiological)

Current Materiel Solutions	Future Materiel Solutions
M93A1 NBC Recon System (Block I) Biological Integrated Detection System	M93A1 NBC Recon System (Block II) Joint Light NBC Recon System (HMMWV/LAV) Chemical Biological Radiological Nuclear (CBRN) Unmanned Ground Reconnaissance (CUGR)

2.1.6 Materiel Solutions Performance Measurements – NBC Reconnaissance (Chemical, Biological, and Radiological)

2.1.6.1 Current Procurement Targets – NBCRS (Block II)

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
M93A1 NBC Recon System (Block II) (Renamed NBCRV)	17	9	8	

2.1.6.2 Current R&D Targets – NBC Reconnaissance Vehicle (NBCRV)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - N/A (Product transition to procurement.) 	<ul style="list-style-type: none"> - Initiated and completed software and hardware upgrades. Hardware upgrades included upgrade of the sensor processing group, and development of a laptop based computer. Software upgrades corrected deficiencies identified during Production Qualification Test (PQT) and Limited User Test (LUT). - Initiated and completed PQT re-testing to support a Low Rate Initial Production (LRIP) Interim Progress Review (IPR).

2.1.6.3 Future R&D Targets – NBCRV

2.1.6.4 Current Procurement Targets – JSLNBCRS

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JSLNBCRS (HMMWV & LAV Variants)	30	14 HMMWV Variant	16 LAV Variant	18 HMMWV Variant 6 LAV Variant

2.1.6.4 Current R&D Targets – Joint Lightweight NBC Reconnaissance System, HMMWV/LAV variants (JSLNBCRS)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Initiate DT I for LAV variant. - Initiate TICs and TIMs software upgrade for CBMS Block II transition to JSLNBCRS procurement. Initiate improvements to biological detection/identification capability. Initiate Non-Traditional Agent (NTA) and chemical vapor algorithm, and start testing - Continue development/design of LAV enhancements, install automatic fire suppression system, LAV Generation II upgrades and test support. - Initiate multiservice Operational Test and Evaluation (MOT&E) planning/coordination. 	<ul style="list-style-type: none"> - Continued LAV development, design, test site planning, development of integrated training package, and logistics planning. - Continued development/design of LAV enhancements, installation of automatic fire suppression system, LAV Generation II upgrades, and test support. - Completed Light Armored Variant (LAV) integration. Initiated the preparation for LAV #1 Engineering Design Test (EDT). Completed Nuclear, Biological, Chemical Detection, Analysis, and Communication Software (NBDCACS) upgrades. - Initiated Toxic Industrial Chemical (TIC) and Toxic Industrial Material (TIM) software upgrade for CBMS Block II transition to JSLNBCRS procurement. Initiated improvements to biological detection/identification capability. - Initiated Multi-service Operational Test and Evaluation (MOT&E) planning/coordination. - Provided government systems engineering support.

2.1.6.5 Future R&D Targets – JSLNBCRS

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Continue TICs and TIMs software upgrades for CBMS Block II transition to JSLNBCRS procurement. Continue improvements to biological detection/identification capability. Initiate Integrated Logistics Support (ILS) of CBMS Block II. - Continue MOT&E planning and preparation. - Continue LAV Developmental Test (DT) of sensors and regression testing. - Complete LAV integration and conduct contractor Engineering Design Test (EDT). - Initiate First Article Test (FAT)/Production Verification Test (PVT) of HMMWV LRIP. - Provide government systems engineering support. 	<ul style="list-style-type: none"> - Complete biological detection capability for CBMS II. - Initiate additional chemical/Toxic Industrial Chemical (TIC) library for CBMS II. - Complete CBMS II software technical transfer and Integrated Logistics Support (ILS). - Provide government systems engineering support.

2.1.6.6 Current R&D Targets – CBRN Unmanned Ground Reconnaissance (CUGR)

FY 2004 Targets	Actual Performance
– FY05 start	–

2.1.6.7 Future R&D Targets – CBRN Unmanned Ground Reconnaissance (CUGR)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - CUGR ACTD - Initiate program management and planning, documentation, Integrated Product Team (IPT) meetings, technical liaisons and transition planning. - CUGR ACTD - Initiate Concepts-of-Operations (CONOP) and techniques, tactics, and procedures (TTP) development, operational test planning and execution. - CUGR ACTD - Initiate JCSD prototyping, technical testing and integration. - CUGR ACTD - Initiate modification of Joint Service Light Nuclear Biological And Chemical Reconnaissance System (JSLNBCRS) shelter design, fabricate and integrate on High Mobility Multipurpose Wheeled Vehicles (HMMWVs). - CUGR ACTD - Initiate CBRN Unmanned Ground Vehicle (CUGV) systems engineering, prototyping, technical testing and integration. 	<ul style="list-style-type: none"> - CUGR ACTD - Continue Concepts-of-Operations (CONOP) and techniques, tactics, and procedures (TTP) development, operational test planning and execution. - CUGR ACTD - Continue Joint Contaminated Surface Detector (JCSD) systems engineering and technical testing. - CUGR ACTD - Complete JCSD prototyping, technical testing and integration. - CUGR ACTD - Continue modification of JSLNBCRS shelter design, fabricate and integrate on HMMWVs. - CUGR ACTD - Continue CBRN Unmanned Ground Vehicle (CUGV) systems engineering, prototyping, technical testing and integration. - CUGR ACTD - Initiate CUGR residual support for extended user evaluation.

2.1.7 Performance Goal 1.4 – Evaluation of Non-Developmental Item (NDI) and Developmental Technologies

Current Materiel Solutions	Future Materiel Solutions
	<ul style="list-style-type: none"> - Non-Traditional Agent (NTA) Detection Improvement Program - Portable Area Warning and Surveillance System (PAWSS) - Point Chemical Agent Detector Evaluation (PCADE) Program - Technology Transfer for Bio Sensors (TT Bio) - Biological Warfare Countermeasures Initiatives (BWC) - Chemical Biological Training System (CBTS) ATD and Chemical Biological Networked Early Warning System (CBNEWS)

2.1.8 Materiel Solutions Performance Measurements – Non-Traditional Agent (NTA) Detection Improvement Program

2.1.8.1 Current R&D Targets – Non-Traditional Agent (NTA) Detection Improvement Program

FY 2004 Targets	Actual Performance
-	<ul style="list-style-type: none"> - NTA - Initiated trade-off studies for Non-Traditional Agents (NTA) to select and test technologies for detection which can be used to augment or improve legacy and developmental detection systems. - NTA - Initiated the integration of existing NTA technologies into legacy and developmental detection systems. Initiated developmental testing using simulants and live agents.

2.1.8.2 Future R&D Targets – Non-Traditional Agent (NTA) Detection Improvement Program

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - NTA - Update trade-off studies to select and test technologies for detection of NTAs which can be used to augment or improve legacy and developmental detection systems. 	<ul style="list-style-type: none"> - NTA - (T&E Capability) Initiate and complete preparation of test methodology, to include design of test set-up and equipment specifications, to test all CBDP systems with non-traditional and emerging

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - NTA - Continue integration of existing selected NTA technologies into legacy and developmental detection systems. Continue developmental testing using simulants and live agents. - NTA - Provide operational assessment/system engineering efforts for NTA enhanced detection systems. 	<ul style="list-style-type: none"> threat agents. - NTA - (T&E Capability) Initiate and complete purchase and assembly of test chamber fixture equipment and modification of existing chambers for multi-agent use. - NTA - (T&E Capability) Initiate and complete validation of test and sampling methods. - NTA - (T&E Capability) Complete integration of existing NTA technologies into legacy and developmental detection systems. - NTA - (T&E Capability) Initiate and complete development of standard operating procedures to include safety, surety, testing methods and data analysis. - NTA - Continue operational assessment/system engineering efforts for NTA enhanced detection systems.

2.1.8.3 Materiel Solutions Performance Measurements – Point Chemical Agent Detector Evaluation (PCADE) Program

2.1.8.4 Current R&D Targets – [PCADE Program](#)

FY 2004 Targets	Actual Performance
-	-

2.1.8.5 Future R&D Targets – Point Chemical Agent Detector Evaluation (PCADE) Program

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - PCADE - Initiate government evaluation of candidate technologies. - PCADE - Initiate systems engineering support. 	-

2.1.8.6 Materiel Solutions Performance Measurements – Technology Transfer for Bio Sensors (TT Bio)

2.1.8.7 Current R&D Targets – [Technology Transfer for Bio Sensors \(TT Bio\)](#)

FY 2004 Targets	Actual Performance
-	-

2.1.8.8 Future R&D Targets – Technology Transfer for Bio Sensors (TT Bio)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - TT Bio - Initiate technology transition, including developmental testing, of capabilities for early warning and detection, detection and identification of biological and chemical agents, including novel threat agents, and decision support tools. - TT Bio - Integrate data from existing biological sensors, medical surveillance, and mobile laboratory systems to detect and confirm releases of biological threat agents. - TT Bio - Integrate processes and report critical information through the Global Command and 	-

FY 2005 Targets	FY 2006 Targets
Control System (GCCS) and into the common operating pictures (COP).	

2.1.8.9 Materiel Solutions Performance Measurements – Biological Warfare Countermeasures Initiatives (BWCI)

2.1.8.10 Current R&D Targets – Biological Warfare Countermeasures Initiatives (BWCI)

FY 2004 Targets	Actual Performance
- N/A	- N/A

2.1.8.11 Future R&D Targets – Biological Warfare Countermeasures Initiatives (BWCI)

FY 2005 Targets	FY 2006 Targets
- Biological Warfare Countermeasures Initiatives (BWCI) - Support United States Pacific Command (PACOM) Biological Warfare Countermeasures Initiative. Conduct fusion cell concept exercise as it transitions from Advanced Technology Development.	- N/A

2.1.8.12 Materiel Solutions Performance Measurements – Chemical Biological Training System (CBTS) ATD and Chemical Biological Networked Early Warning System (CBNEWS)

2.1.8.13 Current R&D Targets – CBTS ATD and CBNEWS

FY 2004 Targets	Actual Performance
- N/A	- N/A

2.1.8.14 Future R&D Targets – CBTS ATD and CBNEWS

FY 2005 Targets	FY 2006 Targets
- N/A	- Chemical Biological Training System (CBTS) ATD - Demonstrate Chemical Biological Training System for use at Ft. Leonard Wood. Initiate Chemical Biological Networked Early Warning System (CBNEWS) using tactical radar for early tactical warning of chemical attack.

2.1.9 Overall Assessment of FY2004 Advanced Development and Procurement Activities for the “Sense” Operational Goal.

Advanced development and procurement efforts in the FY2004 “Sense” operational goal are effective. The program is building on an existing and fielded set of capabilities to provide improved CB detection to the warfighter. DoD provides an integrated collection of programs, research through procurement, to attain performance goals. Procurement and research performance goals for “Sense” have been met and exceeded in Point Detection, Standoff Detection and NBC Reconnaissance.

2.2 OPERATIONAL GOAL 2: SHAPE

Because the FY04 and FY05 budgets were developed prior to the baseline capability assessment, performance goals for battlespace management and battlespace analysis are not identified separately from integrated early warning.

2.2.1 Performance Goal 2.1 – Integrated Early Warning.

Current Materiel Solutions	Future Materiel Solutions
Joint Warning and Reporting Network (JWARN) Block I (Interim Standardization)	JWARN Block II Joint Effects Model (JEM) Block I Joint Effects Model (JEM) Block II Joint Operational Effects Federation (JOEF)

2.2.2 Materiel Solutions Performance Measurements – Integrated Early Warning

2.2.2.1 Current Procurement Targets – Integrated Early Warning

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JWARN	2472	20	45	25
JEM			14	2413

2.2.2.2 Current R&D Targets – JWARN – Block II and III

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Conduct Program Management and Oversight of JWARN and JWARN Initial Capability (JIC) Development efforts. - JIC Component Development. - Plan for and initiate JWARN Developmental Test/Operational Assessment (DT/OA). - Provide integration support for JWARN with Joint Effects Model (JEM) and Joint Operational Effect Federation (JOEF). - Integrate JIC with C4I Systems. - Mission Application Software Integration Support - Operational Assessment Planning - Development of JWARN Communications Interface Device (JCID) 	<ul style="list-style-type: none"> - All targets met.

2.2.2.3 Future R&D Targets – JWARN – Block II and III

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JWARN - Continue Block II development. - JWARN - Continue Block II DT/OA planning. - JWARN - Continue program management and oversight. 	<ul style="list-style-type: none"> - Complete Block II development. - Conduct Block II Developmental Test (DT). - Conduct Block II Interoperability Tests (IOT). - Conduct Joint Component Interface Device (JCID) tests. - Develop comprehensive DT test results and reports. - Conduct Multi-Service Operational Test & Evaluation (MOT&E) event planning. - JCID functionality - design & integration. - Stand alone variant development. - Network Centric Enterprise Services (NCES) / Net Ready (NR) / Key Performance Parameters (KPP) enhancements. - Continue program management and oversight. - (T&E Capability) - Develop, design and integrate software and hardware for a functional Operational Test (OT) Stimulator demonstration system. - (T&E Capability) - Develop a high bandwidth data transfer backbone to transmit and integrate test data for rapid analysis across multiple users and test sites.

2.2.2.4 Current R&D Targets – Joint Effects Model (JEM) Block I and II

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Complete development of logistics/training plans and materials. Complete Post Deployment Software Support (PDSS) plans. Support continued warfighter Integrated Process Team (IPT) involvement and conduct Milestone (MS) B - Award contract for formal software development. Finalize service command and control system integration plans. Complete formal software development. Perform contractor level software testing. Initiate integration activities with Service Global Command and Control System (GCCS) variants and other Command and Control (C2) systems. Verify system interoperability requirements. - Develop detailed Developmental and Operational test plans. Perform Independent Validation & Verification (IV&V) activities during software development. Update the Test and Evaluation Master Plan (TEMP) and the Verification Validation and Accreditation (VV&A) plan to support MS C. Complete data gap analysis of CBRN/TIC/TIM field trials. Produce IV&V exhibits to support class accreditation. Initiate Government Developmental Testing. 	<ul style="list-style-type: none"> - JEM Block I - Completed the TEMP and further refined the operational assessment and formal test plan. Developed the developmental test plan. Initiated joint interoperability test planning and increased developmental test lab capabilities. Coordinated developmental and operational test events. Initiated a test data gap analysis on CBRN field trials to assess the necessity of further field trial requirements. Selected an Accreditation Agent and initiated development of an Accreditation Plan. - JEM Block I - Contractor completed development of engineering builds and initiated development of formal JEM Baseline. Completed Preliminary and Critical Design Reviews. Developed software system engineering documentation. Completed two of five planned development spirals. - JEM Block I - Developed detailed Developmental and Operational test plans. Performed IV&V activities during software development. Updated the TEMP and the VV&A plan to support MS C. Completed data gap analysis of CBRN/TIC/TIM field trials. Produced IV&V exhibits to support class accreditation. Initiated Government Developmental Testing. - JEM Block I - Initiated development of JEM computer based training / courseware. Continued planning for the software support activity and 24/7 help desk support. Conducted joint service reviews of engineering documentation. - JEM Block I - Completed required program documentation and attained Milestone B. Performed Information Assurance Assessment. Reviewed and assessed independent model analysis report and initiated acquisition of proprietary source code. - JEM Block I - Generated integrated architecture artifacts (operational, system, and technical views) and updated logistics documentation. Completed the IV&V plan. Continued IV&V activities including detailed physics-based comparison of software to published algorithms. Continued technical data transition of legacy software system models. - JEM Block II - Completed Block II Focused Technology Assessment. Conducted Request For Information process, convening oversight panel to examine all current technologies. Held multiple review meetings to produce a new Independent Model Assessment Report.

2.2.2.5 Future R&D Targets – JEM Block I and II

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JEM Block I - Continue conduct of Independent Validation and Verification (IV&V). Prepare for and achieve Class Accreditation. - JEM Block I - Continue software development and initiate Government developmental testing. Finalize operational test plans. Initiate Operational Testing (OT). Provide program financial management, scheduling, planning and reporting. - JEM Block I - Perform software maintenance in support of Developmental Testing (DT) and OT. Initiate establishment of the Software Support Activity (SSA). 	<ul style="list-style-type: none"> - JEM Block I - Perform software maintenance through Initial Operational Capability (IOC). - JEM Block I - Initiate long-term field trials, in conjunction with other programs, to obtain highly characterized CBRN dispersion patterns across the spectrum of operational scenarios critical to fill known data gaps. - JEM Block I - Conduct MS C. Finalize Computer Based Training and courseware. Complete infrastructure and stand up of Software Support Activity and 24/7 capable Help Desk. - JEM Block I - Implement and certify the CBRN Database. Provide program financial management, scheduling, planning and reporting. - JEM Block I - Accomplish full system interoperability with JWARN. Complete interoperability, network and system security certifications on 12 different Service C4I/host Systems and two computer operating systems (Windows NT and Unix). Conduct Follow-on Operational Test and Evaluation. - JEM Block II - Revalidate Block II technology analysis from FY04 (See JEM portion of Project CA5), develop prototype options for down-select and prepare for Block II MS B. - JEM Block II - Initiate and complete Block II system development and demonstration, incorporating Urban Missile Defense, Missile Intercept, Backtracking to Source, STRATCOM Support and Human Effects. Migrate Block II technologies into Block I design (Urban Missile Defense, Missile Intercept, Backtrack to Source, STRATCOM Requirements, effects to 180 days, and a 10% improvement in speed and accuracy. Initiate IV&V. - JEM Block II - Initiate Pre-planned Product Improvement (P3I).

2.2.2.6 Current R&D Targets – Joint Operational Effects Federation (JOEF)

FY 2004 Targets	Actual Performance
-	<ul style="list-style-type: none"> - JOEF Block I. Began transition from Advanced Technology Development (ATD). Awarded a BAA contract for prototype development. Developed JOEF prototype based on JOEF Operational Requirements Document (ORD), Concept of Operations (CONOPS), Conceptual Model and Focused Technology Assessment report on fixed sites and medical capabilities. Developed interoperability and integration specifications for interfacing to JEM, JWARN and database management system. Conducted Focused Technology Assessments on capabilities for mobile force missions. Established an earned value management system (EVMS) process.

2.2.2.7 Future R&D Targets – Joint Operational Effects Federation (JOEF)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JOEF Block I - Conduct Interim Progress Review (IPR). Perform financial management, scheduling, planning, and financial and technical reporting. Use the EVMS process. Complete M/S B acquisition documentation. - JOEF Block I - Continue development of prototype. Enhance APOD and medical capabilities. Add Sea Ports of Debarkation (SPOD) capabilities. Design open C4ISR architecture. Interface with standard Geographic Information Systems (GIS). Begin process of generating data tables in support of mobile force assessments using models that support the operational commands. Fund the System Engineering, Test and Evaluation, Warfighter and Logistics IPTs. - JOEF Block I - Initiate design of mobile force and automated TTP capabilities to the prototype. Begin development of Graphical User Interface (GUI) compatible with JEM and JWARN. Improve the post-process capabilities for the JOEF Measures of Effectiveness. Conduct MS B and transition program to system development and demonstration (SDD). 	<ul style="list-style-type: none"> - In all FY 2006 JOEF Planned Program Bullets: "For operational levels of war,..." - JOEF Block 1 - ...in support of deliberate planning: continue SPODs, APODs and automated TTPs software development. - JOEF Block 1 - ...in support of deliberate planning: initiate the development of mobile force capability to meet the Services' requirements. - JOEF Block 1 - ...continue the integration with JEM, JWARN and data base management system. - JOEF Block 1 - ...referencing deliberate planning data, continue APODs, SPOD's and automated TTPs, and initiate mobile force software development for crisis planning. - JOEF Block 1 - ...develop COE interfaces for above functions. - JOEF Block 1 - ...develop test, validation and verification plans, start Development Testing (DT) and begin software validation and verification. - JOEF Block 1 - ...conduct Systems Engineering, Warfighter, T&E, and logistics IPT's. - JOEF Block 1 - ...conduct market research for capabilities that can provide additional capabilities for JOEF and develop training material.

2.2.3 Overall Assessment of FY2004 Advanced Development and Procurement Activities for the “Shape” Operational Goal.

Advanced development and procurement efforts in the FY2004 “Shape” operational goal are effective. The program is building on an existing and fielded set of capabilities to provide improved battlespace management/analysis and integrated early warning to the warfighter in the context of chemical and biological defense. DoD provides an integrated collection of programs, research through procurement, to attain performance goals.

Overall, performance goals for “Shape” have been exceeded. JWARN has transitioned to procurement (despite lagging quantities). Research performance goals have been exceeded with JWARN Blk II and in the field of warfighter risk management tools via the Joint Effects Model (JEM) and Joint Operational Effects Federation (JOEF).

2.3 OPERATIONAL GOAL 3: SHIELD

2.3.1 Performance Goal 3.1 – Respiratory and Ocular Protection.

Current Materiel Solutions	Future Materiel Solutions
M40/M40A1 Mask M42 Tank Mask (Legacy) MCU-2A/P Mask (Legacy)	Joint Service General Purpose Mask (JSGPM)
Aircrew Eye/Respiratory Protective Mask (AERP)- Legacy System CB Respiratory System M45 Aviation Protective Mask M48 Apache Mask (Legacy System)	Joint Service Aircrew Mask (JSAM)
	Joint Service Chemical Environment Survivability Mask (JCESM) (See JSGPM)
M41 Protective Assessment Test System (PATS)	Joint Service Mask Leakage Tester (JSMLT) Miniaturized / Lightweight / Improved PATS

Note: The M41 PATS will be replaced by the JSMLT beginning in FY03.

2.3.2 Materiel Solutions Performance Measurements – Respiratory and Ocular Protection

2.3.2.1 Current Procurement Targets -- Respiratory and Ocular Protection

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JSGPM	0	14,491	65,861	190,000
JSAM	0	0	0	550
M41 PATS	0	2,280	0	
Joint Service Mask Leakage Tester	482	19	240	182

2.3.2.2 Current R&D Targets – JSGPM

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue System Demonstration. System Demonstration includes system support packages for Production Qualification Testing and Initial Operational Testing and Evaluation. - Continue preparation of program/project documentation. Documentation includes the MANPRINT Plan, and Performance Specifications. - Continue Developmental and Operational Testing. Generate test incident reports and corrective action plans to address test results during mask design and prototype production. - Continue Logistics Support Planning. This effort includes development of manuals, and finalization of supportability plans. - Complete development of the JCESM as a lightweight complement to the JSGPM against limited threats. - Initiate support for the development of the Improved Protective Mask (IPM). 	<ul style="list-style-type: none"> - All targets met.

2.3.2.3 Future R&D Targets – JSGPM

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Complete System Demonstration. System Demonstration includes system support packages for PQT and Multiservice Operational Testing and Evaluation. - Complete preparation of program/project documentation. Documentation includes the SAMP and performance specifications. - Complete Development (PQT) and Operational (Limted User Team) Testing. Complete test and 	

FY 2005 Targets	FY 2006 Targets
<p>evaluation reports. Purchase 1000 test articles (at \$150 each, for a total of \$150,000) for Multiservice Operational Test and Evaluation.</p> <p>Complete developmental Logistics Support Planning. This effort includes completion of manuals, and finalization of supportability plans.</p>	

2.3.2.4 Current R&D Targets – Joint Service Aircrew Mask (JSAM)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue system design, engineering and fabrication activities; develop production processes and plan for adequate tooling in preparation for fabrication of units. - Continue contractor and government developmental test and evaluation planning activities, to include integration with selected aircraft. - Continue program management, logistics and sustainment planning. Prepare program and technical documentation. 	<ul style="list-style-type: none"> - All targets met. - Continued system design, engineering and fabrication activities of the two major JSAM variants (Type I – rotary wing and Type II - fixed wing), to include helmet mounted display units; developed production processes and planned for adequate tooling in preparation for fabrication of units.

2.3.2.5 Future R&D Targets – Joint Service Aircrew Mask (JSAM)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Complete Contractor Developmental Testing (DT) for the JSAM rotary wing aircraft variant (Type I), to include the Apache variant (Type Ia), and initiate Government DT. Complete material purchase, fabrication, and assembly of JSAM filters, as well as 121 JSAM Apache DT units (at an average unit cost of \$2141), and 185 JSAM Type I DT units (at an average unit cost of \$1858). Continue documentation and planning in preparation for JSAM Operational Testing (OT). - Continue system design, engineering and fabrication activities for JSAM Type I and Type II variants, to include helmet mounted display variants; continue to develop production processes and ensure tooling and equipment are adequate to fabricate units. - Continue contract and government program management, logistics and sustainment planning. 	<ul style="list-style-type: none"> - Complete Government DT and evaluation for the JSAM rotary wing aircraft variation (Type I), to include the Apache variant (Type Ia). Initiate Government OT, utilizing Type I and Type Ia JSAM DT assets. Continue Government DT and OT planning for fixed wing (Type II), HMD variants. - Continue system design, engineering and fabrication activities on all required variants; continue to develop production processes and ensure tooling and equipment are adequate to fabricate production units. - Continue contract and government program management, logistics and sustainment planning.

2.3.3 Performance Goal 3.2 – Percutaneous Protection.

Current Materiel Solutions	Future Materiel Solutions
<p>Battledress Overgarment (Legacy System)</p> <p>Saratoga, JS Lightweight Integrated Suit Technology (JSLIST)</p> <p>Black Vinyl Overboots (Service O&M responsibility)</p> <p>7, 14, 25-mil Gloves (Service O&M responsibility)</p>	JSLIST, Block I & II Glove Upgrade and Alternative Footwear Systems/Integrated Footwear System (AFS/IFS)
<p>Aircrew Uniform Integrated Battledress (AUIB) (Legacy system)</p> <p>Chemical Protective Undercoverall (Service O&M responsibility)</p> <p>CWU-66/77 Aircrew Ensemble (Legacy system)</p>	Joint Protective Aircrew Ensemble (JPACE)

2.3.4 Materiel Solutions Performance Measurements

2.3.4.1 Current Procurement Targets – Percutaneous Protection

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JSLIST Overgarment	271,183	177,604	290,495	122,644
JSLIST Multi-Purpose Overboot (MULO)		400,000		
JSLIST Glove Block I		201,238		
JPACE			26,649	37,404

2.3.4.2 Current R&D Targets – JSLIST, Block I & II Glove Upgrade and Alternative Footwear Systems/Integrated Footwear System (AFS/IFS), MPS

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Block II Glove Upgrade - Complete IOT&E and initiate chemical validation testing. - Block II Glove Upgrade - Conduct preparations for MS C Low Rate Initial Production (LRIP). - MPS - Complete air/ground operational tests and complete MS C. - MULO - Form alternative footwear solutions project team, conduct market survey, form acquisition strategy, initiate durability and chemical testing. 	<ul style="list-style-type: none"> - JSLIST Block II Glove Upgrade (JB2GU) and Alternative Footwear Systems/Integrated Footwear System (AFS/IFS) - JB2GU and AFS - Initiated developmental testing. - JB2GU and AFS - Conducted preparations for MS C Full Rate Production (FRP). - JB2GU and AFS - Formed project teams, conducted market surveys, prepared acquisition strategies. - JSLIST IFS - Formed project teams, conducted market surveys, prepared acquisition strategies.

2.3.4.3 Future R&D Targets – JSLIST, Block I & II Glove Upgrade and Alternative Footwear Systems/Integrated Footwear System (AFS/IFS)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JB2GU and AFS - Complete chemical agent validation testing and complete IOT&E. - JB2GU and AFS - Complete preparations for MS C Full Rate Production (FRP). - IFS - Complete durability testing, complete IOT&E. 	<ul style="list-style-type: none"> - JSLIST - Initiate hierarchical requirement and affordability analysis. New materials with new designs present trade-offs in about every area of capability. This effort will weigh warfighter requirements in order to ensure that all material and design selections can be traced to the improvements in operational capability most in demand. - JSLIST - Design a new protective suit to support Special Forces operational requirements. U.S. Special Operations Command and JSLIST Additional Source Qualification (JASQ) efforts. - JSLIST - Conduct producibility/reproducibility production base analysis. This effort includes all configuration management work and the work necessary to ensure that the design is producible (and reproducible with minimum variance) with new production methodologies. - JSLIST - Initiate testing of design variations at the system level in aerosol and vapor system test laboratories with U.S. military personnel (only simulants are used). - JSLIST - Conduct initial design field testing. This field-testing will allow informed design selection decisions.

2.3.4.4 Current R&D Targets – JPACe

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue combined DT/OT with durability and other system level testing, including chemical Man in Simulant Test (MIST), aerosol test, and swatch test. Develop and test contaminated doffing procedures, and acquire final safe-to-fly decision from the services. - Prepare for Independent Operational Test & Evaluation (IOT&E). Conduct Milestone (MS) C decision for LRIP of ensembles. - Award contract option to manufacture LRIP ensembles. - Continue developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Update and finalize garment specifications and patterns based on DT/OT results. 	<ul style="list-style-type: none"> - Continued combined DT/OT with durability and other system level testing, including chemical Man in Simulant Test (MIST), aerosol test, and swatch test. Developed and tested contaminated doffing procedures, and acquired final safe-to-fly decision from the services. - Prepared for Independent Operational Test & Evaluation (IOT&E). Purchased 500 test articles (at \$591 each) for IOT&E. Continued developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Updated and finalized garment specifications and patterns based on DT/OT results.

2.3.4.5 Future R&D Targets – JPACe

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Finalize program, logistics, and technical documentation required to ensure that ensembles are fully supported. - Complete IOT&E. Conduct MS C decision for LRIP of ensembles. Prepare documentation for contract option to manufacture LRIP ensembles. - Finalize garment specifications and patterns. Conduct System Verification Review (SVR). Complete MS C for full Rate Production (FRP) design. 	<ul style="list-style-type: none"> - N/A

2.3.5 Performance Goal 3.3 – Expeditionary Collective Protection.

Current Materiel Solutions	Future Materiel Solutions
Various Gas-Particulate Filter Unit (GPFU) configurations (Legacy systems) Modular Collective Protection Equip. (Legacy systems) Selected Area CPS, Ship CPE, (Legacy systems) Ship CPS Backfit	Joint CP Equipment (JCPE) Shipboard Collective Protection Equipment (SCPE)
M20A1 SCPE (Legacy system) Portable CPS (Legacy system)	Joint CP Equipment
CB Protective Shelter (CBPS)	Joint Expeditionary Collective Protection (JECP)
Chemically Protected Deployable Medical Shelter (CPDEPMEDS)/ Chemically Hardened Air Transportable Shelter (CHATH)	CP Field Hospitals (CPFH)

2.3.6 Materiel Solutions Performance Measurements – Expeditionary Collective Protection

2.3.6.1 Current Procurement Targets Measurements – Expeditionary Collective Protection

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
Ship CPS Backfit (protective zones backfitted)	5	5	4	3
CBPS	22	26	100	21
JCPE		631	2,053	
CP Field Hospitals (CPFH)				2

2.3.6.2 Current R&D Targets – Joint Collective Protection (CP) Equipment (JCPE)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Complete development and testing of a Collectively Protected Expeditionary Latrine (CPEL) for the Collectively Protected Expeditionary Medical Support (CPEMEDS). Complete development and testing of a modified M28 liner for large capacity shelters. Complete development and testing to increase efficiency of collective protection system supply fan motors to operate at peak performance over the entire range of filter loading. Complete live agent testing of improved 100/200 cubic feet per minute (CFM) gas filters. Complete testing of developmental prototypes of a suite of improved airlocks to reduce purge times and provide simultaneous entry/exits for all existing CB shelter systems. Complete integration and testing of a Tunnel Airlock Litter Patient (TALP) with a Modular General Purpose Tent System (MGPTS). - Continue program management and IPT support. Continue design and testing of improvements to liner material, construction, and enclosures. - Initiate testing to determine effectiveness of CB shelters while subjected to extreme environmental conditions. Complete development and testing of an individual distribution breathing air hose. Complete development and testing of a filter moisture indicator. Initiate development and testing of a small shelter system (SSS) contamination control area (CCA) and airlock integration. Complete development of shipboard CP automation. Initiate development and testing of a collective protection blast operational analysis. 	<ul style="list-style-type: none"> - Completed development and testing of a CPEL for the CPEMEDS. Completed development and testing of a modified M28 liner for Large Capacity Shelters (LCS). Completed development and testing to increase efficiency of collective protection system supply fan motors to operate at peak performance over the entire range of filter loading. Completed testing of improved airlock doors systems to increase durability and life cycle costs for all existing CB shelter systems utilizing the Bump Through Door Airlocks. - Continued program management and IPT support. Continued design and testing of improvements to liner material, construction, and enclosures. Continued live agent testing of improved 100/200 CFM gas filters. Continued integration and testing of a TALP with a MGPTS. - Completed a study to determine if CB shelters should be tested for extreme environmental conditions. Completed identification and testing of a second source for individual distribution breathing air hose. Completed development and testing of a filter moisture indicator. Completed development of shipboard CP automation. Initiated development and testing of an SSS CCA and airlock integration. Initiated development and testing of collective protection system blast operational mitigation techniques. Initiated comprehensive engineering study and analysis of the Collective Protection Equipment (CPE) systems used with the Patriot Missile system to evaluate and investigate potential upgrades/improvements using current technologies. Initiated development and testing of a re-designed CPEMEDS collective protection liner systems for use in the Chemically Protected Deployable Medical Systems (CPDEPMEDS) version of the SSS.

2.3.6.3 Future R&D Targets – Joint Collective Protection (CP) Equipment (JCPE)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Complete design and testing of improvements to liner material, construction, and enclosures. Complete live agent testing of improved 100/200 CFM gas filters. Complete integration and testing of a TALP with a MGPTS. Complete development and testing of a SSS CCA/airlock integration. Complete development and testing of collective protection system blast operational mitigation techniques. Complete comprehensive engineering study and analysis of the collective protection equipment (CPE) systems used with the Patriot Missile system to evaluate and investigate potential upgrades/improvements using current technologies. Complete development and testing of a re-designed CPEMEDS collective protection liner systems for use in the CPDEPMEDS version of the SSS. - Continue program management and IPT support. Initiate development and testing of 100/200 CFM gas filters to provide protection against selected Toxic Industrial Chemicals (TICs). 	<ul style="list-style-type: none"> - Complete development and testing of 100/200 CFM gas filters to provide protection against selected TICs. Continue program management and IPT support. - Complete development and testing to increase efficiency of collective protection system supply fan motors to operate at peak performance over the entire range of filter loading. Complete development and testing of collective protection system, operational blast mitigation techniques. Continue program management and IPT support.

2.3.6.4 Current R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2004 Targets	Actual Performance
– N/A (Preparing to transition to procurement).	

2.3.6.5 Current R&D Targets – Joint Expeditionary Collective Protection (JECP)

FY 2004 Targets	Actual Performance
– N/A	– N/A

2.3.6.6 Future R&D Targets – Joint Expeditionary Collective Protection (JECP)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> – N/A 	<ul style="list-style-type: none"> - JECP - Establish a Project Management Office (PMO) and System Engineering, Product Support, and Test & Evaluation Integrated Product Teams (IPT). Institute associated charters identifying roles and responsibilities. Initiate development of a Single Acquisition Management Plan (SAMP), that will provide a permanent record of all relevant program information in a single document - JECP - Conduct a tailored Analysis of Alternatives (AoA) leveraging the market survey, test results and lessons learned from the FY05 Collective Protection (ColPro) Technology Readiness Evaluation (TRE). Collaborate with the JRO Shield Integrator in preparing acquisition documentation and decision review package for Milestone (MS) A. - JECP - Provide PMO and subject matter expert support to the Joint Requirements Office (JRO) in development of the Concept of Operation (ConOps) and the Capability Development Document (CDD). Develop the Systems Engineering Management Plan (SEMP) and the initial Test & Evaluation Master Plan (TEMP) along with requisite MS B

FY 2005 Targets	FY 2006 Targets
	<p>documentation, including but not limited to: the Acquisition Strategy, APB, Programmatic Environment Safety and Occupational Health Evaluation (PESHE), Logistics Analysis, Program Protection Plan, and a validated Life Cycle Cost Estimate.</p> <ul style="list-style-type: none"> - JECP - Translate the JRO/User developed ConOps and CDD into a Work Breakdown Structure leading to a Statement of Objectives (SOO) and a Performance Specification (P-Spec). Establish a Risk Management Plan and conduct an initial risk analysis. Award a prototype development contract. Initiate DT testing of prototypes.

2.3.7 Performance Goal 3.4 – Medical Prophylaxes.

Current Materiel Solutions	Future Materiel Solutions
Medical Biological Licensed Anthrax vaccine Licensed Smallpox vaccine	Biological Defense Vaccines, e.g., Multivalent Equine Encephalitis, Recombinant Botulinum AB, Plague, Staphylococcal Enterotoxin B (SEB), Ricin and Next Generation Anthrax vaccine Biological Process Development ParalellaVax Rapid Vaccine Testing Technology study
Medical Chemical Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) (Service O&M responsibility)	Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) Vesicant Prophylaxis Cyanide Pretreatment

2.3.8 Materiel Solutions Performance Measurements – Medical Prophylaxes

2.3.8.1 Current Procurement Targets Measurements – Medical Prophylaxes

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
Anthrax Vaccine Doses		1,818,000	2,803,685	1,180,337
Smallpox Vaccine Doses		700,000		

2.3.8.2 Current R&D Targets – Biological Defense Vaccines

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Recombinant Botulinum Vaccine - Continue non-clinical studies and final container stability testing (Block I). - Submit IND application (Block I). - Initiate Phase 1 clinical trial execution and monitoring (Block I). - Initiate process validation, to include qualification and validation of fermentation and purification processes and manufacture of serotypes A and B (Block I). - Assay development, small-scale process development and manufacture of cell banks for serotypes C, E, and 	<ul style="list-style-type: none"> - Recombinant Botulinum Vaccine - Continued non-clinical studies and final container stability testing for serotypes A and B. - Submitted IND application for serotypes A and B. - Initiated Phase 1 clinical trial execution and monitoring for serotypes A and B. - Initiated process validation, to include qualification and validation of fermentation and purification processes for the manufacture of serotypes A and B. - Initiated manufacturing scale-up on serotypes A and B. Performing manufacturing scale-up resulted in significant cost avoidance over the life of the

FY 2004 Targets	Actual Performance
F (Block II).	program. Fewer lots will have to be produced and tested to meet the troop equivalent dose (TED) requirements.
<u>Equine Encephalitis Vaccines</u>	<u>Biological Process Development</u> <ul style="list-style-type: none"> - Initiated polyclonal antibody production for proof of concept in non-clinical trials for botulinum antitoxin.
<p><u>Equine Encephalitis Vaccines</u></p> <ul style="list-style-type: none"> - Complete assay development and qualification and complete lot release testing on the cGMP pilot lot. - Initiate Phase 1 clinical trial on the VEE vaccine. - Submit IND application for V3526 vaccine. - Complete cGMP lot for clinical use. 	<u>Equine Encephalitis Vaccines</u> <ul style="list-style-type: none"> - Completed VEE 1 AB vaccine cGMP lot for clinical use - Submitted IND application for the VEE 1 AB vaccine. - Initiated Phase 1 clinical trial on the VEE 1 AB vaccine.
<u>Plague Vaccine</u>	<u>Plague Vaccine</u> <ul style="list-style-type: none"> - Continue stability testing and initiate animal testing. - Manufacture cGMP pilot lot and 3 qualification lots. - Complete toxicology and immunogenicity testing. - Prepare and submit IND application to FDA. - Conduct Phase I clinical trial and perform animal efficacy studies on the UK vaccine candidate in order to collect data for a down-select decision.
<u>Next Generation Anthrax Vaccine</u>	<u>Next Generation Anthrax Vaccine</u> <ul style="list-style-type: none"> - Continue Phase 1 clinical trial.
	<ul style="list-style-type: none"> - Completed initiation of Phase 1 clinical trial. - Continued studies for alternative delivery systems including oral adjuvants and development of an orally delivered anthrax-plague vaccine.

2.3.8.3 Future R&D Targets – Biological Defense Vaccines

FY 2005 Targets	FY 2006 Targets
<u>Recombinant Botulinum Vaccine</u>	<u>Recombinant Botulinum Vaccine</u> <ul style="list-style-type: none"> - Initiate Phase 2 clinical trial. - Continue non-clinical studies and stability testing. - Complete manufacturing process validation and initiate consistency lot production. - Complete Phase 1 clinical trial and continue non-clinical studies, which will transition to System Development and Demonstration (SDD).
<p><u>Equine Encephalitis Vaccines</u></p> <ul style="list-style-type: none"> - N/A 	<ul style="list-style-type: none"> - Equine Encephalitis Vaccines - Initiate manufacturing process validation. - Complete Phase 1 clinical trial on the VEE 1 AB vaccine. - Initiate Phase 2 clinical trial immunological testing. - Initiate passive transfer studies with samples from the Phase 2 clinical trial.
<p><u>Plague Vaccine</u></p> <ul style="list-style-type: none"> - Complete toxicology testing. - Conduct Phase 1 clinical trial of US candidate. - Continue non-clinical studies to include animal efficacy studies on US candidate. 	<ul style="list-style-type: none"> - Plague Vaccine - Complete Phase 1 clinical trial of US candidate. - Continue full-scale manufacturing process development of US candidate. - Continue non-clinical studies of US candidate and

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Continue stability testing on US candidate. - Initiate Phase 2 clinical trial on US candidate. - Continue full-scale manufacturing process development of US candidate. 	<ul style="list-style-type: none"> - transition into System Development and Demonstration (SDD). - Continue stability testing of US candidate. -
<ul style="list-style-type: none"> - Ricin Vaccine - N/A 	<ul style="list-style-type: none"> - Ricin Vaccine - Initiate technology transfer from the technology base to advanced development. Transfer will consider several possible candidates, to include genetically modified variants. - Initiate assay development for vaccine candidate. - Initiate manufacturing process development for vaccine candidate.
<ul style="list-style-type: none"> - ParalellaVax Rapid Vaccine Testing Technology study - Conduct ParalellaVax Rapid Vaccine Testing Technology study. 	<ul style="list-style-type: none"> - ParalellaVax Rapid Vaccine Testing Technology study

2.3.8.4 Current R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2004 Targets	Actual Performance
<i>Pyridostigmine Bromide</i>	<i>Pyridostigmine Bromide</i> <ul style="list-style-type: none"> - Completed human serum study. - Continued ex vivo human muscle and non-human primate studies to demonstrate efficacy vs. surrogate markers.
	<i>Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP)</i> <ul style="list-style-type: none"> - SNAPP - Continued FDA required post approval studies.
<i>SERPACWA</i>	<i>SERPACWA</i> <ul style="list-style-type: none"> - Completed production line process validation and field trials. - Continued FDA manufacturing requirements, redesigned packaging for field durability, and shelf-life monitoring. - Conducted packaging engineering study.

2.3.8.5 Future R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2005 Targets	FY 2006 Targets
<i>Pyridostigmine Bromide</i>	
<ul style="list-style-type: none"> - Complete FDA post-approval studies (ex vivo human muscle and non-human primate studies to demonstrate efficacy vs. surrogate markers). 	
<i>Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP)</i>	
<ul style="list-style-type: none"> - SNAPP - Complete FDA required post approval studies. 	
<i>SERPACWA</i>	
<ul style="list-style-type: none"> - Complete FDA manufacturing requirements, redesign packaging for field durability and shelf-life monitoring - Continue FDA required post-marketing studies (including compatibility study with M291). 	

2.3.8.5 Performance Goal 4.10 Medical post treatments for CW agents.

Current Materiel Solutions	Future Materiel Solutions
Nerve Agent Antidote Kit (NAAK)* Convulsant Antidote Nerve Agent (CANA) * Sodium thiosulfate/nitrate* Multi-chamber Autoinjector*	Vesicant Agent Countermeasures Plasma and Recombinant Bioscavenger (pBSCAV+ rBSCAV) Chemical Surety Facility

*(Service O&M responsibility)

2.3.8.6 Current R&D Targets – Plasma and Recombinant Bioscavenger (pBSCAV+ rBSCAV)

FY 2004 Targets	Actual Performance
- N/A	- N/A

2.3.8.7 Future R&D Targets – Plasma and Recombinant Bioscavenger (pBSCAV+ rBSCAV)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - pBSCAV - Initiate small-scale process development/assay qualification and test/evaluate medical defense products against traditional and non-traditional nerve agents. - Initiate small-scale manufacturing. - Initiate Investigational New Drug (IND) application. 	<ul style="list-style-type: none"> - rBSCAV - Initiate small-scale process development/assay qualification and test/evaluate medical defense products against traditional and non-traditional agents. - Initiate pre-clinical safety studies. - Initiate Investigational New Drug (IND) application. - Complete IND application. - Continue small-scale manufacturing. - Initiate and complete pre-clinical safety studies. - Initiate Phase 1 clinical safety study.

2.3.8.8 Current R&D Targets – Chemical Surety Facility

FY 2004 Targets	Actual Performance
- N/A	- N/A

2.3.8.9 Future R&D Targets – Chemical Surety Facility

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Chemical Surety Facility - Initiate test and evaluation of medical chemical defense products under GLP conditions in a chemical agent research and development facility against non-traditional agents. 	<ul style="list-style-type: none"> - Chemical Surety Facility - Continue test and evaluation of medical chemical defense products under Good Laboratory Practices (GLP) conditions in a chemical agent research and development facility.

2.3.9 Overall Assessment of FY2004 Advanced Development and Procurement Activities for the “Shield” Operational Goal.

Advanced development and procurement efforts in the FY2004 “Shield” operational goal are effective. The program is building on an existing and fielded set of capabilities to provide improved CB protection to the warfighter. DoD provides an integrated collection of programs, research through procurement, to attain performance goals. Targeted procurement and research performance goals for “Shield” have been met and exceeded in Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, and Medical Prophylaxis.

2.4 OPERATIONAL GOAL 4: SUSTAIN

2.4.1 Performance Goal 4.1 – Individual Decontamination.

Current Materiel Solutions	Future Materiel Solutions
M291 skin decon kit (Purchase is a Service O&M responsibility)	M291 skin decon kit (Sorbent based)
M295 individual equipment decon kit (Purchase is a Service O&M responsibility)	M295 individual equipment Decon kit (Sorbent based) Joint Service Personnel/Skin Decontamination System (JSPDS)

2.4.2 Materiel Solutions Performance Measurements – Individual Decontamination

2.4.2.1 Current Procurement Targets – Individual Decontamination

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
M291 Skin Decontamination Kit		8,978	40,260	
M295 Equipment Decontamination Kit		6,379		

2.4.2.2 Current R&D Targets – M291 and M295 Decon Kits

FY 2004 Targets	Actual Performance
None	N/A

2.4.2.3 Future R&D Targets – M291 and M295 Decon Kits (Sorbent based)

FY 2005 Targets	FY 2006 Targets
None	None

2.4.3 Performance Goal 4.2 – Equipment Decontamination.

Current Materiel Solutions	Future Materiel Solutions
	M100 Sorbent Decon System (SDS)
M17A2 Lightweight Decon System (Legacy System)	M17A-3 SANATOR (part of the Decontamination Application System)
	Joint Service Sensitive Equipment Decon System (JSSEDS) Block I, II, and III
M12 Power-Driven Decon Apparatus (Legacy system)	Joint Service Family of Decontamination System (JSFDS) - Blocks I, II, and III Joint Service Transportable Decontamination System – Small Scale (JSTD-SM)

2.4.4 Materiel Solutions Performance Measurements – Equipment Decontamination

2.4.4.1 Current Procurement Targets – Equipment Decontamination

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
M100 Sorbent Decon System	24,240	46,278	0	
M17A-3 SANATOR		352		
M12A1 Decontamination Apparatus		174		
Modular Decontamination System	128	0	0	
Joint Service Transportable Decontamination System – Small Scale (JSTD-S)				70
Joint Service Family of Decontaminant Systems (JSFDS) (Note: FY06 funding realigned to a separate JSTD-S program)	392,000	52	298	

2.4.4.2 Current R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue development testing (DT III) to address outstanding safety, wound compatibility and packaging issues. - Initiate JSM-PDS and JSTDs, small-scale and large-scale, DT I downselection testing to include live agent system level testing. - Continue development of program documentation, such as the Request for Proposal, Logistics Support Plan and System Acquisition Management Plan. Manage contracting effort and downselection process. - Perform engineering and logistics trade off studies for the JSM-PDS and JSTDs. - Finalize Test and Evaluation Master Plan (TEMP), down-selection test methodology, System Acquisition Management Plan and Request for Proposal for JSPDS, JSM-PDS and JSTDs to support a Milestone (MS) B decision. - Procure test units for down-selection testing (70 systems at average cost of 60K) - Perform engineering and logistics studies to include an evaluation of alternative means of enhancing decontamination of aircraft to expedite an increase in capability in the near term, to identify potential simulants for use in testing or training and to establish baseline for evaluating improvements in logistics. 	<ul style="list-style-type: none"> - Continued development testing (DT II) to include clinical studies to address long-term safety and initial packaging tests. - Initiated economic analyses of alternative logistics strategies for JSPDS, developed technical manual, training and other logistics support documentation. - Procured test units and decontaminants for down-selection testing (400 systems at average cost of \$40K each) for the JSTDs-SM. - Conducted Source Selection, prepared test sites for conduct of DT I, R-3. - JSFDS/JSTDs-SM - Performed market survey, finalized Test and Evaluation Master Plan (TEMP), performance specification, down-selection test methodology, System Acquisition Management Plan (SAMP) and Request for Proposal for JSTDs Small Scale to support Milestone (MS) B. - JSFDS/JSPDS - Performed compatibility testing of reactive skin decontamination lotion with currently fielded decontaminant to identify and mitigate safety risks to the user. - JSFDS/JSPDS - Finalized TEMP, SAMP and other program documentation to support a MS B decision for transition to SDD. - JSFDS/JPDS - Reviewed feasibility of requirements and established acquisition strategy for the Joint Portable Decontamination System (JPDS). - JSFDS/JSTDs-LG - Reviewed feasibility of requirements and established acquisition strategy for the JSTDs Large Scale. - JSFDS/JSSDS - Evaluated feasibility of meeting JSSDS requirements and established acquisition strategy. - JSFDS - Performed reliability testing of the multi-purpose decontamination system to support the Senior Readiness Oversight Council's urgent need. Performed simulant and live agent decontamination testing and shelf life testing of DF-200.

2.4.4.3 Future R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Complete DT II, including extended packaging testing, material compatibility testing, system level compatibility testing, and field durability developmental testing. - Conduct Performance Based Logistics (PBL) Business Case Analysis to determine optimum logistics support strategy. Update logistics and training documentation based on test results. - Perform an operational assessment on four candidate JSTDs-SM decontamination systems. 	<ul style="list-style-type: none"> - JSFDS-Overarching Decontamination Model throughout RDT&E - Develop a model to predict contamination-caused hazards for all phases of chemical and biological threats. - JSFDS (T&E Capability) - Develop and validate chemical decontamination test methods for full-system tests. - JSPDS - Conduct Initial Operational Test and Evaluation (IOT&E) to support full rate production decision.

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JSFDS/JSTDSSM - Perform down-selection testing (DT I) on four candidate JSTDSSM decontamination systems for Low Rate Initial Production (LRIP) contract award. DT I includes live agent efficacy testing, material compatibility testing, and reliability testing. - JSFDS/JSTDSSM - Develop logistics documentation and perform training to support testing for JSTDSSM. - JSFDS/JSTDSSM - Update SAMP, TEMP and other program documentation to support MS C LRIP for JSTDSSM. 	<ul style="list-style-type: none"> - JSPDS - Update program documentation to support MS C full rate production decision, update logistics support documentation including fielding plans, begin implementation of the support strategy identified by the PBL BCA. - JSTDSSM - FY06 funding realigned to a separate JSTDSSM program.

2.4.4.4 Current R&D Targets – Joint Service Sensitive Equipment Decon System (JSSEDS) Block I

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Complete optimization effort of primary solvent-based system. - Initiate development of pre-cleaning decontamination system to remove gross contamination from sensitive equipment. - Initiate System Development & Demonstration (SDD) Statement of Work. - Develop acquisition documentation support for Increment I of JSSED ORD. - Develop, coordinate and process Increment I Temp 	<ul style="list-style-type: none"> - All targets met.

2.4.4.5 Future R&D Targets – Joint Service Sensitive Equipment Decon System (JSSEDS) Block I

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Finalize planning for DT to include upgrade of test chambers. - Complete optimization effort of primary solvent base system. - Complete the system integration of pre-clean capability and initiate military utility testing. - Prepare documentation for the award of a competitive contract for SDD. - JSSED - Design and fabricate prototypes for Limited Objective Experiment (LOE) (Six units at \$450K each). - JSSED - Conduct LOE and government testing. 	<ul style="list-style-type: none"> - JSSED - Award SDD contract and initiate prototype award.

2.4.4.6 Current R&D Targets – Joint Service Sensitive Equipment Decon System (JSSEDS) Blocks II and III (JPID)

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Continue documentation for Milestone (MS) B. - Initiate support for the Integrated Product Team. - Initiate identification of platform materials compatibility testing. - Initiate market survey for commercial base. - Initiate update Analysis of Alternatives (AoA). - Initiate developmental test (DT) planning. - Initiate Industry Day for exploration of S&T and develop exchange with service/industry. 	<ul style="list-style-type: none"> - All targets met plus initiated planning for characteristic study.

2.4.4.7 Future R&D Targets – JSSEDS Blocks II and III (JPID)

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - Continue support to the IPT including logistics support. - Continue DT and plan for operational testing (OT). - Complete interior platform material identification effort. - Develop the Technology Readiness Evaluation. - Complete documentation for MS B. - Initiate documents/package for MS C. - Complete market analysis. - Complete Industry Day at two sites. - Complete characteristics effort analysis. - Conduct DT to validate market analysis. 	<ul style="list-style-type: none"> - -

2.4.5 Performance Goal 4.3 – Fixed Site Decontamination.

The current approach is being re-evaluated. Fixed site decontamination RDA efforts are being addressed through separate projects, including the Joint Service Man-Portable Decon System, Joint Service Transportable Decon System, Joint Service Stationary Decon System, and the Joint Service Personnel/Skin Decontamination System as well as related ACTD efforts such as the Restoration of Operations (RestOps) ACTD and the Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD.

2.4.6 Materiel Solutions Performance Measurements– Fixed Site Decontamination

2.4.4.6 Current R&D Targets – Joint Service Transportable Decontamination System (JSTD-SM)

FY 2004 Targets	Actual Performance
- (FY06 start)	-

2.4.4.7 Future R&D Targets – Joint Service Transportable Decontamination System (JSTD-SM)

FY 2005 Targets	FY 2006 Targets
-	<ul style="list-style-type: none"> - JSTD-SM - Conduct Initial Operational Test and Evaluation (IOT&E) to support full rate production decision. - JSTD-SM - Perform DT II which includes live chemical and biological agent testing, extensive material compatibility and efficacy testing, environmental testing and shelf-life testing. - JSTD-SM - Update program documentation and obtain full rate Production decision. Conduct Performance Based Logistics (PBL) Business Case Analysis (BCA) to determine optimum logistics support strategy for the JSTD-SM hardware and decontaminant(s). Update logistics and training documentation based on test results. Prepare fielding plans. - JSTD-SM - Procure decontaminants (40,000 gallons) and interim contract support for testing. - JSTD-SM - Develop change packages for detectors to ensure ability to assess success of decontamination operations.

2.4.6.1 Current R&D Targets – Restoration of Operations (RestOps) ACTD

FY 2004 Targets	Actual Performance
- N/A	<ul style="list-style-type: none"> - Restoration of Operations (RestOps) ACTD - Completed procurement and contractor logistics support services for residual support on selected technologies. - RestOps ACTD - Finalized Lessons learned, incorporated into ACTD final report, completed service doctrinal changes and Techniques, Tactics, and Procedures changes.

2.4.6.2 Current R&D Targets – Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD

FY 2004 Targets	Actual Performance
- N/A	<ul style="list-style-type: none"> - CASPOD ACTD (DTO JD23 - Finalized system integration and system test efforts of sensor, alarm, and warning device hardware with Command and Control software. - CASPOD ACTD (DTO JD23) - Performed Military Utility Assessment (MUA) of CASPOD technologies during the CASPOD final demonstration. - CASPOD - Completed techniques, tactics, and procedures for the use of the CASPOD ACTD technologies. Completed training plan and documentation for final demonstration. Conducted program integration tasks. - CASPOD - Initiated transition and residual support planning. Provide logistic support for initial year of residual phase. - CASPOD - Conducted final demonstration, acquired and transported test equipment, cargo containers, vehicles, sealift ship, and provided for travel of users and other logistics support items.

2.4.6.3 Future R&D Targets – Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - CASPOD ACTD (DTO JD23) (BCA#34) - Execute residual support for CASPOD fielded technologies. - (DTO JD23) (BCA#34) - Complete transition planning, acquire logistics support, and comple - 	<ul style="list-style-type: none"> - CASPOD ACTD (DTO JD23) (BCA#34) - Complete procurement and contractor logistics support services for residual support on selected technologies. - CASPOD ACTD (DTO JD23) (BCA#34) - Finalize lessons learned, incorporate into ACTD final report, complete service doctrinal changes and techniques, tactics, and procedures changes. -

2.4.7 Performance Goal 4.4 – Medical Diagnostics.

Current Materiel Solutions	Future Materiel Solutions
None (interim measure- manual medical diagnoses and Theater Army Medical Labs)	Joint Biological Agent Identification and Diagnostic System (JBAIDS)

2.4.8 Materiel Solutions Performance Measurements – Medical Diagnostics

2.4.2.1 Current Procurement Targets – Medical Diagnostics

Systems	FY04		FY05	FY06
	Target	Actual	Target	Target
JBAIDS		25	141	158

2.4.8.1 Current R&D Targets – JBAIDS Blk I

FY 2004 Targets	Actual Performance
<ul style="list-style-type: none"> - Complete DT and Operational Assessment (OA) - Develop hardware and assays; conduct physical configuration audit of the design; deliver test articles; conduct hardware qualification testing; and continue hardware engineering change proposal process, hardware upgrading and BW assay development; review contractor developed technical manuals and training packages. - Submit JBAIDS 510(k) package for anthrax assay for FDA review and clearance. - Initiate Operational Testing (OT) planning efforts. - Critical Reagent Program (CRP): support to JBAIDS includes providing biological agent panels and nucleic acid reference standards 	<ul style="list-style-type: none"> - Continued Developmental Testing (DT). - Developed hardware and assays; delivered test articles; conducted hardware qualification testing; and continued hardware engineering change proposal (ECP) process; initiate hardware upgrading and biological warfare (BW) assay development. - Completed Operational Assessment (OA).

2.4.8.2 Future R&D Targets – JBAIDS

FY 2005 Targets	FY 2006 Targets
<ul style="list-style-type: none"> - JBAIDS Blk I - Complete DT, hardware ECP process and upgrading, and BW assay development. Initiate and complete OT. Achieve Milestone C/LRIP. - Develop contract ECPs. - Conduct New Equipment Training (NET) of systems. - Conduct FDA clinical trials and submit FDA 510(k) for Anthrax. 	<ul style="list-style-type: none"> - JBAIDS Blk II - Award developmental contract and provide incremental funding to support the purchase of development prototype articles (software, reagent kits, extraction kits) to support developmental and operational testing, and to support technical manual development, contractor logistics support, FDA 510(k) activities, and test plans/procedures. - Initiate Developmental Testing (DT) and start planning efforts for Operational Assessment (OA) and Operational Testing (OT). - Initiate Government Furnished Material (GFM) manufacturing support of toxin test sample manufacturing. - Initiate toxin Food and Drug Administration (FDA) interface planning efforts to determine pre-marketing approval (PMA)/510(k) applicability. - Initiate JBAIDS DT system operator and maintenance training efforts.

2.4.9 Performance Goal 4.5 – Medical Therapeutics.

Current Materiel Solutions	Future Materiel Solutions
Medical Biological	
Antibiotics (Service O&M responsibility)	Broad spectrum antibiotics Antitoxins Anti-viral drugs
Medical Chemical	
Antidote Treatment – Nerve Agent Autoinjector (ATNAA)	Improved Nerve Agent Treatment System (INATS) Technology Transfer Medical Systems (TT Med) Advanced Anticonvulsant System (AAS)

2.4.10 Materiel Solutions Performance Measurements – Medical Therapeutics

2.4.10.1 Current R&D Targets – Medical Chemical Therapeutics

FY 2004 Targets	Actual Performance
<u>Advanced Anticonvulsant System (AAS)</u> <ul style="list-style-type: none"> - Continue optimum serum levels of midazolam and neuropathological analysis studies in non-human primate models. - Initiated pre-clinical and acute toxicology studies. - Initiated Phase 1 clinical protocol and Investigational New Drug (IND) application. 	<u>Advanced Anticonvulsant System (AAS)</u> <ul style="list-style-type: none"> - Continued pre-clinical and acute toxicology studies. - Initiated pre-clinical and acute toxicology studies. - Initiated Phase 1 clinical study and Investigational New Drug (IND) application.
<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> <ul style="list-style-type: none"> - Continued shelf-life extension stability studies required by the FDA. 	<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> <ul style="list-style-type: none"> - Completed four-year shelf-life submission to FDA. - Initiated five-year shelf-life studies and FDA required post-marketing studies.
<u>Improved Nerve Agent Treatment System (INATS)</u> <ul style="list-style-type: none"> - Initiate process development/current Good Manufacturing Practices (cGMP) pilot lots and initiate acute toxicology and stability studies. 	<u>Improved Nerve Agent Treatment System (INATS)</u> <ul style="list-style-type: none"> - All targets met.

2.4.10.2 Future R&D Targets – Medical Chemical Therapeutics

FY 2005 Targets	FY 2006 Targets
<u>Advanced Anticonvulsant System (AAS)</u> <ul style="list-style-type: none"> - Continue optimum serum levels of midazolam and neuropathological analysis in non-human primate models and pre-clinical studies. - Complete FDA IND/regulatory strategy and submit IND. - Complete Phase 1 clinical studies. - Continue pre-clinical and acute toxicology studies. - Initiate process development/cGMP manufacturing processes. - Complete Phase 1 clinical studies of anticonvulsant for treatment of non-traditional agent induced seizures. 	<u>Advanced Anticonvulsant System (AAS)</u> <ul style="list-style-type: none"> - Complete optimum serum levels of midazolam and neuropathological analysis studies, pre-clinical and acute toxicology studies. - Initiate Phase 2 clinical studies (definitive clinical efficacy/status epilepticus). - Continue process development/current Good Manufacturing Practices (cGMP) requirements.
<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> <ul style="list-style-type: none"> - Complete five-year shelf-life studies and FDA required post-marketing studies. 	<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u>
<u>Technology Transfer Medical Systems (TT Med)</u> <ul style="list-style-type: none"> - TT Med - Initiate medical technology transition, including clinical trials, of medical countermeasures against biological and chemical agents, including novel threat agents, for therapeutics, prophylaxes and pretreatments, and diagnostics capabilities. 	
<u>Improved Nerve Agent Treatment System (INATS)</u> <ul style="list-style-type: none"> - Continue pre-clinical/animal safety, acute toxicology and stability studies. - Continue process development and current Good Manufacturing Practices (cGMP) requirements. - Initiate non-human primate oxime studies. - Initiate preparation of IND application. - Continue animal studies to demonstrate efficacy 	<u>Improved Nerve Agent Treatment System (INATS)</u> <ul style="list-style-type: none"> - Continue cGMP process development. - Continue non-human primate oxime, pre-clinical/animal safety, acute toxicology, and stability studies. - Continue IND application process.

FY 2005 Targets	FY 2006 Targets
against non-traditional agents.	- Initiate Phase 1 clinical safety study.

2.4.11 Overall Assessment of FY2004 Advanced Development and Procurement Activities for the “Sustain” Operational Goal.

Advanced development and procurement efforts in the FY2004 “Sustain” operational goal are effective. The program is building on an existing and fielded set of capabilities to provide improved CB decontamination and post-contamination medical support to the warfighter. DoD provides an integrated collection of programs, research through procurement, to attain performance goals. Targeted procurement and research performance goals for “Sustain” have been met and exceeded in Individual, Equipment and Fixed Site Decon as well as Medical Diagnostics and Therapeutics.

SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES

3.0 OVERVIEW

The science and technology (S&T) base of the CBDP provides essential capabilities to develop technological advantage over any potential adversaries and prevent technological surprise. Within S&T there are three budget activities and three research areas, and project funding codes for each. (See **Table 1.**)²

Table 1. CBDP Science and Technology Base Project Funding Codes

Budget Activity (Program Element)	Research Area		
	Non-Medical S&T	Medical S&T	
	CB Defense	Chemical Defense	Biological Defense
BA1 - Basic Research (0601384BP)	CB1	TC1	TB1
BA2 - Applied Research (0602384BP)	CB2	TC2	TB2
BA3 - Advanced Technology Development (0603384BP)	CB3, CP3	TC3	TB3

The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of S&T efforts. The long-term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (e.g., number of breakthroughs in basic science made last year.) However, using an approach similar to the performance plans of other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation—there are a variety of qualitative and quantitative performance measures that may be used to demonstrate progress of S&T efforts towards outcomes, which fulfills the requirements of the GPRA.

The basic performance measure established for S&T efforts is the independent expert panel review. The CBDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), has been conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to the Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD.

3.1 CB DEFENSE S&T PLANNING

To ensure U.S. military preeminence in the long term, the Department must continue to focus investments on new generations of defense technologies. The Defense Science and Technology Strategy, with its supporting Basic Research Plan, Joint Warfighting Science and Technology Plan, and Defense Technology Area Plan, is the foundation of the science and technology (S&T) program. The Office of the Secretary of Defense, the Joint Staff, the military departments, and the defense agencies collaboratively develop the S&T program. Objectives of S&T planning are to:

- ensure projects support warfighter requirements,
- identify gaps in existing defense and commercial research,
- ensure collaborative planning and execution of the S&T program,

² Biological Warfare Defense programs funded under DARPA project BW-01 are not addressed in this performance plan except for those projects identified as Defense Technology Objectives.

- reduce undesired duplication of effort,
- provide the basis for independent expert panel reviews.

3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM

This section provides the objectives and metrics for the overall CB defense S&T program. An overall assessment is provided below. Actual and planned performance on specific projects is detailed in the following sections on S&T.

3.2.1 CB Defense Science and Technology Outcome Measure

CB Defense S&T is...	...minimally effective when...	...successful when...
	<ul style="list-style-type: none"> • All major commodity areas are rated GREEN and no sub-areas are rated RED by the TARA panel. • Research efforts contribute to increased knowledge regarding CB threats and science and technologies to defend against these threats. • Projects support goals and timelines stated in planning documents, specifically the <i>Joint Warfighting Science and Technology Plan</i> and the <i>Defense Technology Area Plan</i>. 	<ul style="list-style-type: none"> • All commodity areas are rated GREEN by the TARA panel. • New capabilities are successfully demonstrated and transition to advanced development.

3.2.1.1 Metric Description. The metric for science and technology base projects is a qualitative assessment of the results of basic research, applied research, and advanced technology development compared to their intended purposes. This qualitative methodology for measuring the outcomes of the science and technology base is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of research efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) This approach is similar to those used in the performance plans other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation. Qualitative performance measures are provided for each of the projects listed in table 1. Qualitative performance measures are assessed by an independent panel as well as by the accomplishment of specific project targets identified and detailed in each of the project areas below. The assessment includes an evaluation of the information provided to determine whether it is sufficient to allow for an accurate, independent determination of the program activity's performance. An important element of the research efforts—especially for basic and applied research—is the evaluation and elimination of unsuccessful technologies. While not always identified as a specific target, the scientific method contributes to increased knowledge by eliminating efforts that will not contribute to project objectives.

3.2.1.2 Validation and Verification Methodology. The basic performance measure established for S&T efforts is the *independent expert panel review*.³ This complies with White House guidance to ensure that independent assessments of research programs evaluate both the quality of programs and progress of research towards stated goals.⁴ The CBDP has adopted this

³ *Evaluating Federal Research Programs: Research and the Government Performance and Results Act*, Washington, D.C: National Academy Press, 1999.

⁴ See memorandum from The White House, Neal Lane and Jacob J. LE, "Follow-On Guidance for FY 2001 Interagency Research and Development Activities," June 8, 2000.

practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), is conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to the Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD. **Table 2** provides a summary of the assessment of each of the commodity areas within the CBDP, and table 3 provides the assessment by the TARA Panel of each of the DTOs presented during the FY04 review.

Table 2. 2004 TARA Assessment of CB Defense S&T Commodity Areas

CB Defense Science and Technology Commodity Area	TARA Rating
DETECTION	YELLOW
PROTECTION	GREEN
MEDICAL CHEMICAL DEFENSE	GREEN
MEDICAL BIOLOGICAL DEFENSE	YELLOW
DECONTAMINATION	GREEN
INFORMATION SYSTEMS TECHNOLOGY	GREEN

3.2.2 Assessment of CB Defense Science and Technology Outcome Measure

Overall, the DoD CBDP science and technology base has been effective. Most areas have been rated green by the TARA panel. In addition, there were several technologies that completed successful demonstrations over the past year, and as detailed in the following sections, there are several examples of technology transitions to advanced development.

3.3 DEFENSE TECHNOLOGY OBJECTIVES (DTOs)

The Department's commitment to transforming U.S. military forces requires robust and stable funding for the S&T program. S&T expenditures support basic research as well as focused investments guided by DTOs. DTOs provide a framework for S&T efforts by identifying:

- What specific technologies will be developed and/or demonstrated.
- What specific milestones are to be reached, using what approaches.
- Which customers will benefit.
- What specific benefits the customers will gain.
- What level of funding will be programmed and from what sources.
- What quantitative metrics will indicate progress.

Within the CBDP, DTOs fund approximately one-third of S&T efforts. DTOs are the building blocks of the defense S&T Program. They represent only high priority Service and Defense Agency programs, consistent with the Defense Planning Guidance and the Defense S&T Strategy. DTOs are one of the key S&T planning tools. They are used to assist in planning and programming S&T funds, they help in articulating key efforts and goals, and they provide a key performance measure for contribution of the S&T effort to warfighter needs. All updates, changes, and approvals of DTOs are made by the Defense Science and Technology Advisory Group (DSTAG), the senior S&T advisory body within the Department. Assessments of DTO performance are provided annually by the TARA.

The CBDP S&T efforts continue to demonstrate new capabilities for the warfighter. Progress of DTOs is shown in the following tables. Progress in other portions of S&T is shown in section 3.4. For FY04, 57% of the DTOs were rated green, which was less than the target of

80%. Several factors contributed to these ratings, including: (1) pursuit of leading edge research, which included accepting technical risks on several projects, (2) aggressive scheduling of milestones by the DTO managers, and (3) more realistic assessment of costs, schedules, and technical performance by the TARA panel. The TARA Panel made specific recommendations on each of the DTOs that were not rated green, and they will review and assess these efforts in FY05.

Table 3. Status of Defense Technology Objectives as Rated by the Chemical and Biological Defense Technology Area Review and Assessment

	FY04	FY05	FY06	
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	57	80	80
Total Number of DTOs	25 of 31	20 of 35	44 of 35	

* Six CBD DTOs were rated as yellow [Y] and one as red [R].

Table 4. 2004 TARA Rating of Chemical and Biological Defense DTOs

DTO No.	DTO Title	TARA Rating
CB.08	Advanced Absorbents for Protection Applications	GREEN
CB.20	Automated Genetic Identification	NOT RATED
CB.24	Medical Countermeasures for Encephalitis Viruses	NOT RATED
CB.27	Therapeutics Based on Common Mechanisms of Pathogenesis	GREEN
CB.30	Medical Countermeasures for Vesicant Agents II	NOT RATED
CB.31	Medical Countermeasures for Brucellae	NOT RATED
CB.32	Alternative Delivery Methods for Recombinant Protein Vaccines	GREEN
CB.34	Recombinant Plague Vaccine Candidate	NOT RATED
CB.35	Standoff Biological Aerosol Detection	YELLOW
CB.36	Universal End-of-Service-Life Indicator for NBC Mask Filters	GREEN
CB.37	CB Agent Water Monitor	YELLOW
CB.38	Activity-Based Detection and Diagnostics	NOT RATED
CB.40	Immune Building Program	GREEN
CB.42	Environmental Fate of Agents	YELLOW
CB.43	Chemical and Biological Warfare Effects on Operations	GREEN
CB.44	Oxidative Formulation	YELLOW
CB.45	Self-Detoxifying Materials for CB Protective Clothing	YELLOW
CB.46	Recombinant Ricin Vaccine	GREEN
CB.47	Improved Immunodiagnostic Platform	GREEN
CB.48	Improved Oxime	GREEN
CB.50	Lightweight Integrated CB Detection	GREEN
CB.51	Low-Level CW Agent Exposure: Effects and Countermeasures	GREEN
CB.52	Detection of CB Contamination on Surfaces	RED
CB.53	Wide-Area Aerial Reconnaissance for Chemical Agents	YELLOW
CB.54	Therapy for Smallpox and other Pathogenic Orthopoxviruses	GREEN
CB.55	Chemical and Biological Hazard Environment Prediction	GREEN
CB.56	Methodology for BWA Detection and Med Diagnostic Systems	GREEN
CB.57	Non-Traditional Nerve Agent Medical Countermeasures	GREEN
CB.58	Western and Eastern Equine Encephalitis Vaccine	GREEN
CB.59	Therapeutic Strategies for Botulinum Neurotoxins	GREEN
CB.60	Vaccine technologies for Protection Against Filovirus Exposure	GREEN

DTO No.	DTO Title	TARA Rating
CB.62	Hazard Prediction with Nowcasting	GREEN
CB.63	Therapeutic Strategies for Treating Filovirus Infection	GREEN
JD.13	Terrorist CB Countermeasures	NOT RATED
JD.23	Contamination Avoidance at Seaports of Debarkation ACTD	NOT RATED

3.3.1.1 Metric Description. Table 4 lists specific DTOs assessed during 2004. Detailed descriptions of these DTOs are found in The DoD CBDP Annual Report to Congress, Annexes A–E. Each DTO is reviewed annually by an independent peer review panel, called the Technology Area Review and Assessment (TARA) panel. The goal is to have at least 80% of the DTOs rated green. The total number of DTOs varies per year based on new DTO assignments and completion of DTO efforts. Total DTO funding varies per year and may represent between 25%–50% of total science and technology base funds. During the 2004 TARA, 7 CBD DTOs were rated as yellow and one as red. Table 5 provides a summary explanation DTOs or technology areas listed in Tables 2 and 3 that were not rated green.

Table 5. Summary of Explanations for Selected 2004 TARA CB Defense DTOs

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.35 Standoff Biological Aerosol Detection	YELLOW	<ul style="list-style-type: none"> •Strengths: <ul style="list-style-type: none"> –Leveraged controlled experiments to obtain data for better modeling. –Showed bio simulant (BG) could be separated from other materials. •Finding: <ul style="list-style-type: none"> –Coherent Technologies Inc. (CTI) technologies may not be mature enough to meet objectives. <ul style="list-style-type: none"> •Exploring other wavelength regimes might allow more flexibility for technical options (leverage medical free electron laser facilities). –Limited algorithm development. –Simulant testing may be limiting. –Systems level modeling was deficient. Recommendation: <ul style="list-style-type: none"> –Apply Recommendation B. –For CTI technology, explore cooperative research with DoD Medical Free Electron Laser (MFEL) facilities.
CB.37 CB Agent Water Monitor	YELLOW	<ul style="list-style-type: none"> •Finding: <ul style="list-style-type: none"> –Finding C: No single technology meets the requirements for CB detection in water. Therefore, a systems integration and modeling effort is needed. –Sequential filtering may not be sufficient to achieve concentrator goals. –False alarm rate (5%) is very high. Whole system issue is based on false alarm rate, and there appeared to be no plan for solving this problem. Recommendation: <ul style="list-style-type: none"> Reliance Panel give this important effort management attention in the area of systems analysis and modeling in order to optimize success.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.42 Environmental Fate of Agents	YELLOW	<p>Finding:</p> <ul style="list-style-type: none"> –Not likely to complete work within schedule. May need to extend by at least one year. Wind tunnels have yet to be validated and will be critical. –Evaporation model should be able to leverage existing research outside of CB defense (i.e., the extensive literature on wind flow over flat surfaces (and other geometries) and mass and thermal exchanges). Wind sheer and mass transfer problems should be better understood. –Did not present evidence of incorporation of fundamental fluid mechanics. –Modeling may need to drive experimental design. While statistical parameterization bounded the number of experiments, it is hard to tell how well it can predict outside of experimental matrix. Room for a much more fundamental approach. –Need to coordinate with the Army Corps of Engineers soils group. –Scaling from wind tunnels to field trials may be problematic and require complex validation studies not currently envisioned. <p>Recommendation:</p> <ul style="list-style-type: none"> –Reliance Panel Chair take action to convene a “Science & Engineering Oversight Committee” as soon as possible to review the new program structure, redirected activities, and accompanying rationale. Ensure that committee membership includes expertise in mass transport and fluid mechanics for the purpose of assessment of the approach to predictive modeling and interpretation of results.
CB.44 Oxidative Formulation	YELLOW	<p>Finding:</p> <ul style="list-style-type: none"> –Roadmap presented in previous TARAs indicated that a disciplined approach to decon formulation development is possible. –2004 technical presentation was not linked to the roadmap, and therefore the apparent narrow focus of the technology candidate (Decon Green) had limited justification. –Apparent material incompatibility of Decon Green with some materials, such as rubber, gaskets, and seals, is an area of serious concern. –Not yet addressing environmental (EPA regulatory) and toxicology issues. –Remaining issue with 35% H₂O₂—both transportation and stability? –One solution may not (ever) be possible. A multi-solution approach may be needed. <p>Recommendation:</p> <ul style="list-style-type: none"> –Reliance Panel Chair take action to evaluate the technical content and goals of the program and its management.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.45 Self-Detoxifying Materials for CB Protective Clothing	YELLOW	<p>•Strengths:</p> <ul style="list-style-type: none"> –Good collaboration with industry sources for both fabric and potential antimicrobials. –Demonstrated effectiveness of chloroamines and quaternary amines as antimicrobial agents. <p>•Finding:</p> <ul style="list-style-type: none"> –Detox of biological agents may be too hard of a problem. Progress on and concepts for chemical detox seem reasonable. Unclear as to the requirement for biological agent detox. <p>Recommendation:</p> <ul style="list-style-type: none"> –Reliance Panel Chair, in coordination with JRO, consider limiting scope of this DTO to chemical detoxifying materials. –Apply Recommendation G. –Reliance Panel Chair, in coordination with JRO, consider limiting scope of this DTO to chemical detoxifying materials. –Apply Recommendation G.
CB.51 Low-Level CW Agent Exposure: Effects and Countermeasures	YELLOW	<p>•Strengths:</p> <ul style="list-style-type: none"> –Important program for integrating both the medical and non-medical communities and for models of agent effects. <p>•Finding:</p> <ul style="list-style-type: none"> –Cross validation studies will be critical and are both a project management and a research design/execution challenge. <p>Recommendation:</p> <ul style="list-style-type: none"> –Reliance Panel Chair and DTO Manager institute an appropriate management structure including quarterly IPRs and appropriate advisory groups.
CB.52 Detection of CB Contamination on Surfaces	RED	<p>•Finding:</p> <ul style="list-style-type: none"> –Go back to a more principle-driven approach requiring more fundamental research before technology development. Couldn't explain down-select process/criteria. May need to break DTO into many parts, based on surfaces, CONOPs, agent(s) to be detected. Sever chemical and biological detection objectives. Need to be closely linked to the Agent Fate Program. –2003 TARA Issue not clearly addressed -- Use modeling to define and optimize performance parameters within the applicable trade spaces. –Technology appears to be too immature to meet objectives within schedule. –FY04 limited budget = Red. Do not expect much progress with such significant cuts. Also, unrealistic ramp in FY05 to 10x the FY04 budget. Need to re-structure start up in the absence of any previous systems level modeling. Why are DTO funds not protected? Could funds be replaced with other money? <p>Recommendation:</p> <ul style="list-style-type: none"> –Apply Recommendation B. –Present DTO restructuring plan to appropriate decision authority.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.53 Wide-Area Aerial Reconnaissance for Chemical Agents	YELLOW	<p>•Strengths:</p> <ul style="list-style-type: none"> –Making good use of models and existing data bases for real background. –Demonstrated high speed interferometry. <p>•Finding:</p> <ul style="list-style-type: none"> –Algorithm development is lagging. –Technology robustness – only vapor, underestimated clutter, urban backgrounds, etc. –Unclear that technology is mature enough to transition in FY06. If tech performance is not there, then schedule is at risk also. –May be vulnerable to deliberate countermeasures, such as deliberate use of simulants. –Availability of platforms will be critical. Systems level modeling was deficient.

3.3.1.2 V&V Methodology. Each TARA team includes about ten members, including experts from outside the Department. The non-DoD members include experts in relevant fields from other U.S. government agencies, private industry, and academia. The TARA team assesses DTOs in terms of three factors—budget, schedule, and technical performance—and assign the programs a Red, Yellow, or Green rating based on how well they are progressing toward their goals. The assessment of technical performance includes a qualitative assessment of how risk is managed, especially for innovative or leading edge research that may involve high technical risk. This method of peer review is accepted and endorsed by the S&T stakeholders. Adjustments are made to program plans and budgets based on the ratings awarded. The following criteria are used in assigning ratings:

- Green – Progressing satisfactorily toward goals.
- Yellow – Generally progressing satisfactorily, but some aspects of the program are proceeding more slowly than expected.
- Red – Doubtful that any of the goals will be attained.

The DTO ratings are semi-quantitative metrics, reflecting the opinions of independent experts. The DTOs contain quantitative metrics, which provide a basis for determining progress of that effort towards a warfighter payoff.

3.4 BASIC RESEARCH (PROGRAM ELEMENT 0601384BP)

This program element (PE) funds the Joint Service core research program for CB defense (medical and non-medical). The basic research program aims to improve the operational performance of present and future DoD components by expanding knowledge in relevant fields for CB defense. Moreover, basic research supports a Joint Force concept of a lethal, integrated, supportable, highly mobile force with enhanced performance by the individual soldier, sailor, airman, or marine. Specifically, the program promotes theoretical and experimental research in the chemical, biological, medical, and related sciences. Research areas are determined and prioritized to meet Joint Service needs as stated in mission area analyses and Joint operations requirements, and to take advantage of scientific opportunities. Basic research is executed by academia, including Historically Black Colleges and Universities and Minority Institutions (HBCU/ MIs), and government research laboratories. Funds directed to these laboratories and research organizations capitalize on scientific talent, specialized and uniquely engineered facilities, and technological breakthroughs. The work in this program element is consistent with

the Joint Service Nuclear, Biological, and Chemical (NBC) Defense Research, Development, and Acquisition (RDA) Plan. Basic research efforts lead to expeditious transition of the resulting knowledge and technology to the applied research (PE 0602384BP) and advanced technology development (PE 0603384BP) activities. This project also covers the conduct of basic research efforts in the areas of real- time sensing and diagnosis and immediate biological countermeasures. The projects in this PE include basic research efforts directed toward providing fundamental knowledge for the solution of defense- related problems and new- improved military capabilities, and therefore, are correctly placed in Budget Activity 1.

3.4.1 CB Defense Basic Research (Project CB1)

This project funds basic research in chemistry, physics, mathematics, life sciences, and fundamental information in support of new and improved detection technologies for biological agents and toxins; new and improved detection technologies for chemical threat agents; advanced concepts in individual and collective protection; new concepts in decontamination; and information on the chemistry and toxicology of threat agents and related materials.

3.4.1.1 CB1 Performance Goal (Outcome). The goal of the CB defense non-medical basic research program is to increase scientific understanding of the mechanisms and processes involved in the detection, protection against, and decontamination of chemical and biological warfare agents.

3.4.1.2 CB1 Outcome Measure

CB1 is minimally effective when	CB1 is successful when
<ul style="list-style-type: none"> • The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> – biosensors, – aerosol sciences, – chemistry and toxicology of bioactive compounds, – thin film technology development, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – biological point detection, – protection, – decontamination, – simulants, – information technology • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> • Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.1.3 CB1 Actual and Planned Performance

FY2004 Targets	Actual Performance
<u><i>Biological Agent Identification Detection</i></u> Complete proof of principle experimentation; complete theoretical correlations to experimental data for POE. Continue synthesis of candidate stochastic sensor elements; continue screening testing. Demonstrate proof of principle for separation of BW agent surrogates. Complete initial investigations of the relationships between physical-chemical properties and optical separation of biological agent simulants. Continue investigations of micro-channel mixing via configurable heating and sur-	<u><i>Biological Agent Identification Detection</i></u> - Completed proof of principle experimentation; completed theoretical correlations to experimental data for Polarization Opposition Effect. Continued synthesis of candidate stochastic biosensor elements; continued screening testing. Demonstrated proof of principle for separation of BW agent surrogates using optical pressure. Continued investigations of micro-channel mixing via configurable heating and surfaces by comparison of data and model prediction. Initiated investigations of

FY2004 Targets	Actual Performance
<p>faces by comparison of data and model prediction. Initiate investigations of antimicrobial peptides for applicability as bio-detection elements; initiate testing program. Initiate effort to characterize polymorphic regions of <i>B. mallei</i> genome using ribotyping, repetitive sequence polymerase chain reaction, and Randomly Amplified Polymorphic DNAs.</p>	<p>antimicrobial peptides for applicability as bio-detection elements; initiated testing program. Initiated effort to characterize polymorphic regions of <i>B. mallei</i> genome using ribotyping, repetitive sequence polymerase chain reaction, and Randomly Amplified Polymorphic DNAs.</p> <p><u>Brooks City Base Biotechnology</u> - Investigated technologies for Brooks City Base Biotechnology.</p> <p><u>Fluorescence Activated Sensing Technology (FAST)</u> - Investigated technologies for Fluorescence Activated Sensing Technology.</p> <p><u>Biodetection Research</u> - Investigated technologies for biodetection.</p>
<p><u>Chemical Stand-off Detection</u> - Complete investigations of the applicability of new techniques to the analysis and processing hyperspectral Fourier Transform Infrared data. Complete investigations of novel two-photon fluorescence spectroscopy method and potential applicability to stand-off CB detection. Transition to BA2 as appropriate</p>	<p><u>Chemical Stand-off Detection</u> - Completed investigations of the applicability of new techniques to the analysis and processing hyperspectral Fourier Transform Infrared data. Completed investigations of novel two-photon fluorescence spectroscopy method and potential applicability to stand-off CB detection</p>
<p><u>Integrated CB Detection</u></p> <p>Complete proof of principle investigations of novel materials for selective interactions with CW agent simulants in conjunction with optical amplification to enhance detection. Complete investigations of surface modified gold nanoclusters for detection of CW agents. Initiate investigations of modified nanofilaments for detection of CB warfare agents.</p>	<p><u>Integrated CB Detection</u> - Completed proof of principle investigations of novel materials for selective interactions with CW agent simulants in conjunction with optical amplification to enhance detection. Continued investigations of surface modified gold nanoclusters for detection of CW agents. Initiated investigations of modified nanofilaments for detection of CB warfare agents.</p> <p><u>Detection of Biological Agents in Water</u> - Investigated technologies for the detection of biological agents in potable water sources.</p>
<p><u>Solution Decontamination</u> - Initiated investigations of and developed methodology for determination of the chemical structure semi-solid materials with absorbed CB agents. Initiated studies of the decontamination mechanism of secondary catalytic oxidants generated by the addition of monovalent salts to a peracid-dioxirane. Initiated investigations of the efficacy of artificial nucleases for anti-bacterial and anti-viral activity. Initiated investigations of the utility of high-field Nuclear Magnetic Resonance (NMR) methodology in conjunction with tandem mass spectrometry to determine structures of biologically derived toxins. Continued investigations of chemical strategies designed for fast dissolution and deactivation/destruction of CW agents rapidly in organic nanoemulsions.</p>	<p><u>Solution Decontamination</u> - Completed feasibility studies for determination of semi-solid materials chemical composition with absorbed CB agents. Completed studies of the decontamination mechanism of secondary catalytic oxidants generated by the addition of monovalent salts to a peracid-dioxirane. Completed investigations of the efficacy of artificial nucleases for anti-bacterial and anti-viral activity. Completed investigations of the utility of high-field Nuclear Magnetic Resonance (NMR) methodology in conjunction with tandem mass spectrometry to determine structures of biologically derived toxins. Completed investigations of chemical strategies designed for dissolution and deactivation/destruction of CW agents rapidly in organic nanoemulsions.</p>
<p><u>Sensitive Equipment Decontamination</u> - Initiated investigation of efficacy of vaporous dimethyl dioxirane for decontamination of BW agents.</p> <p><u>Nanoemulsions for Decontamination</u> - Developed and validated the efficacy of nanoemulsions for the purpose of decontaminating biological threat agents. The nanoemulsion can be formulated into a cream, liquid, or</p>	<p><u>Sensitive Equipment Decontamination</u> - Completed investigation of efficacy of vaporous dimethyl dioxirane for decontamination of BW agents.</p>

FY2004 Targets	Actual Performance
spray.	
<u>Respiratory Protection</u> - Complete theoretical and empirical investigations of the mechanisms of interactions of vapors with active surfaces.	<u>Respiratory Protection</u> Completed theoretical and empirical investigations of the mechanisms of interactions of vapors with active surfaces.
<u>Individual Protection (Clothing)</u> - Evaluate effectiveness of nanofiber-coated fabrics for protection against particulate materials. Complete investigations of surface modified membranes.	<u>Individual Protection (Clothing)</u> Evaluated effectiveness of nanofiber-coated fabrics for protection against particulate materials. Completed investigations of protection afforded by a novel surface modified membrane.
<u>Shelter Protection</u> Initiate investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning.	<u>Shelter Protection</u> Initiated investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning.
<u>Chemical Threat Agents</u> - Investigate CW agents volatility in humidified air.	<u>Chemical Threat Agents</u> - Continued investigations of CW agent (HD) blister volatility in humidified air.

3.4.1.4 CB1 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>Biological Agent Identification Detection</u> Biological Agent Identification Detection - Complete testing of candidate ion channel stochastic sensor elements. Complete investigations of micro-channel mixing via configurable heating and surfaces. Complete development of test articles and procedures. Continue testing of antimicrobial peptides. Continue effort to characterize polymorphic regions of <i>B. mallei</i> genome using ribotyping, repetitive sequence polymerase chain reaction, and randomly amplified polymorphic DNAs. Initiate effort to assess recombinant single-domain antibodies for bio-detection. Initiate effort to assess utility of modified nanowires for biodetection. Initiate effort to assess novel light-scattering method for bio-identification. Initiate effort to enhance utility of microfluidic control for bio-detection. Initiate investigations of bacterial ghosts as simulants for biological warfare agents.	<u>Biological Agent Identification Detection</u> Complete effort to characterize polymorphic regions of <i>B. mallei</i> genome using ribotyping, repetitive sequence polymerase chain reaction, and randomly amplified polymorphic DNAs. Continue effort to assess recombinant single-domain antibodies for bio-detection. Continue effort to assess utility of modified nanowires for biodetection. Continue effort to assess novel light-scattering method for bio-identification. Continue effort to enhance utility of microfluidic control for bio-detection. Continue investigations of bacterial ghosts as simulants for biological warfare agents.
<u>Integrated CB Detection</u> Continue investigations of modified nanofilaments for the detection of CB agents. Initiate novel approaches for improved CB detection	<u>Integrated CB Detection</u> Complete investigations of modified nanofilaments for the detection of CB agents.
<u>Respiratory Protection</u> Initiate research into understanding physical adsorption processes for toxic industrial chemicals and CW agents on novel adsorption materials. Initiate effort to develop performance model for the electric-swing adsorption process.	<u>Respiratory Protection</u> Continue research into understanding physical adsorption processes for toxic industrial chemicals and CW agents on novel adsorption materials. Continue to develop performance model for the electric-swing adsorption process.
<u>Shelter Protection</u> Continue investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning; expand this effort to include permeation performance evaluations of related polymeric materials. Initiate efforts to assess utility of nanoparticle-modified fibers for denaturing CWA	<u>Shelter Protection</u> Continue investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning; expand this effort to include permeation performance evaluations of related polymeric materials. Continue effort to assess utility of nanoparticle-modified fibers for denaturing CWA

FY 2005 Targets	FY 2006 Targets
<p><u>Decontamination</u> Initiate research effort to assess potential of ionic liquids for agent decontamination capability. Initiate research effort to assess potential of metal catalysis for agent decontamination capability.</p>	<p><u>Decontamination</u> Continue research effort to assess potential of ionic liquids for agent decontamination capability. Continue research effort to assess potential of metal catalysis for agent decontamination capability.</p>
<p><u>Chemical Threat Agents</u> Complete effort to measure ambient volatility of CWA. Complete investigations of modified gold anosensors.</p>	<p><u>Supporting Science and Technology</u> Initiate effort to develop predictive model for ambient volatility and agent simulant properties and characteristics.</p>
<p><u>Information Systems Technology</u> Initiate basic research and science efforts in support of modeling agent dispersal after release.</p>	<p><u>Information Systems Technology</u> Initiate basic research in the area of fourth dimensional contaminant plume interpolation and continue efforts in support of modeling agent dispersal after release.</p>

3.4.1.5 Assessment of CB Defense Basic Research. Basic research efforts in FY04 for project CB1 were effective. The program completed most major targets and all Congressionally directed programs were successfully executed during FY04. Additional work was performed in the area of Brooks City Base Biotechnology, Fluorescence Activated Sensing Technology (FAST), Biodetection Research, and Detection of Biological Agents in Water. Extensive research continues to be conducted in several research areas to include Biological Agent Identification Detection, Integrated CB Detection, Shelter Protection, and Chemical Threat Agents. These research areas are intended to support several major operational goals detailed in Section 2 of the performance plan. Several new research projects are being initiated in FY05, in the areas of Decontamination and Information Systems Technology.

3.4.2 Medical Biological Defense Basic Research (Project TB1)

This project funds basic research on the development of vaccines and therapeutic drugs to provide effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. This project also funds basic research employing biotechnology to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include current science and technology program areas in medical biological defense diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines) and directed research efforts.

3.4.2.1 TB1 Performance Goal (Outcome). The goal of medical biological defense basic research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of diseases caused by biological warfare (BW) agents, and the preventive, therapeutic, and diagnostic sciences underlying the technologies to counter these threats.

3.4.2.2 TB1 Outcome Measure

TB1 is minimally effective when	TB1 is successful when
<ul style="list-style-type: none"> The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> Bacterial Therapeutics, Bacterial Vaccines, Toxin Therapeutics, Toxin Vaccines, Viral Therapeutics, Viral Vaccines, Diagnostic Technologies, 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development

TB1 is minimally effective when	TB1 is successful when
<ul style="list-style-type: none"> – Laboratory-based and Analytical Threat Assessment Research. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	

3.4.2.3 TB1 Actual and Planned Performance

FY2004 Targets	Actual Performance
<p><i><u>Diagnostic Technologies</u></i></p> <p>Continue basic research on new diagnostic approaches to the early recognition of infection focusing on technologies compatible with future comprehensive integrated diagnostic systems. Continue to develop reagents and assays for appropriate biological markers for early recognition of infection and identify new host and agent-specific biological markers. Continue research directed toward new technological approaches for diagnosis of biological threat agents and new sample processing technologies.</p>	<p><i><u>Diagnostic Technologies</u></i> - Conducted basic research on new diagnostic approaches to the early recognition of infection; developed reagents and associated assays to aid in identifying new host and agent-specific biological markers that can be used for early recognition of infection. Continued research to develop, evaluate, and explore new technological approaches for diagnosis of potential biological warfare threat agents and for concentrating and processing clinical samples to support rapid identification and diagnostics.</p>
<p><i><u>Therapeutics, Anthrax studies</u></i> - Continue extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus will continue on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on an enzyme target, NADs, which is critical for the germination and vegetative life cycle of <i>B. anthracis</i>.</p>	<p><i><u>Therapeutics, Anthrax Studies</u></i> - Continued extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus continued on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on the enzyme target nicotinamide adenine dinucleotide (NAD), which is critical for the germination and vegetative life cycle of <i>Bacillus anthracis</i>, the etiologic agent for anthrax.</p>
<p><i><u>Therapeutics, Bacterial</u></i></p> <p>Evaluate novel lead antimicrobial compounds in small animal models for anthrax and plague.</p>	<p><i><u>Therapeutics, Bacterial</u></i> - Evaluated novel lead antimicrobial compounds in small animal models for anthrax and plague.</p>
<p><i><u>Therapeutics, Toxin</u></i></p> <p>Continue custom synthesis of structural analogs of lead compounds identified by high-throughput screening assays for botulinum and SE toxins. Refine x-ray data for toxin-inhibitor co-crystal structures of most promising botulinum neurotoxin and SE inhibitors. Perform computational chemistry studies to refine lead compound co-crystal structures.</p>	<p><i><u>Medical Biological Warfare Defense, Engineered Pathogen Identification and Countermeasures Program (Bug to Drug)</u></i> - Identified the impact of biowarfare pathogens on the human body using computer models and direct protein analysis. Continued to develop counteracting drugs based on a comprehensive understanding of how the potential drug candidates impact the human body, outside of their desired effect against the pathogen.</p> <p><i><u>Therapeutics, Toxin</u></i> - Continued custom synthesis of structural analogs of lead compounds identified by high-throughput screening assays for botulinum and SE toxins. Refined x-ray data for toxin-inhibitor co-crystal structures of most promising botulinum neurotoxin and SE inhibitors. Performed computational chemistry studies to refine lead compound co-crystal structures.</p>
<p><i><u>Therapeutics, Viral</u></i></p>	<p><i><u>Therapeutics, Toxin, Bioprocessing Facility</u></i></p> <p>Developed a detailed design for the construction of a current Good Manufacturing Practice (cGMP) compliant facility capable of producing human monoclonal antibodies (MAbs) to botulinum neurotoxins (BoNT) for use in phase I clinical trials.</p> <p><i><u>Therapeutics, Viral</u></i> – Continued research for</p>

FY2004 Targets	Actual Performance
Continue research for development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Complete research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target. Generate baculovirus-expressed Ebola virus proteins for use in research studies. Identify sequences within Ebola virus genes that are highly susceptible to short interfering RNA-mediated degradation.	development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Completed research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target. Generated baculovirus-expressed Ebola virus proteins for use in research studies. Identified sequences within Ebola virus genes that are highly susceptible to short interfering RNA-mediated degradation.
<i>Vaccines, Bacterial</i> Continue studies on the molecular mechanisms of pathogenesis of selected BW threat agents. Identify additional virulence determinants of Brucella species. Initiate a study to identify and characterize novel virulence proteins of <i>F. tularensis</i> .	<i>Vaccines, Bacterial</i> - Continued studies on the molecular mechanisms of pathogenesis of selected BW threat agents. Identified additional virulence determinants of Brucella species. Initiated a study to identify and characterize novel virulence proteins of <i>F. tularensis</i> .
<i>Vaccines, Toxin</i> Conduct computational chemistry studies to develop next generation botulinum neurotoxin and recombinant ricin toxin A-chain (rRTA) vaccines. Evaluate theoretical feasibility of multivalent vaccines by protein engineering. Evaluate the role of glycosylation or other structural modifications in reducing efficacy of botulinum neurotoxin vaccines.	<i>Vaccines, Toxin</i> – Conducted computational chemistry studies to develop next generation botulinum neurotoxin and recombinant ricin toxin A-chain (rRTA) vaccines. Evaluated theoretical feasibility of multivalent vaccines by protein engineering. Evaluated the role of glycosylation or other structural modifications in reducing efficacy of botulinum neurotoxin vaccines.
<i>Vaccines, Viral</i> Complete investigating the role of cytotoxic T cells in the Ebola virus-mouse model. Examine the use of virus-like particles (VLP) as antigen for vaccines for filoviruses. Initiate research to investigate the role of cytotoxic T cells in the filovirus model in non-human primates.	<i>Vaccines, Viral</i> - Completed investigating the role of cytotoxic T cells in the Ebola virus-mouse model. Examined the use of virus-like particles (VLP) as antigen for vaccines for filoviruses. Initiate research to investigate the role of cytotoxic T cells in the filovirus model in non-human primates.
<i>Vaccines, Plant Vaccine Development</i> Develop plant-based subunit vaccines as countermeasures against biological warfare agents.	<i>Vaccines, Plant Vaccine Development</i> - Developed plant-based subunit vaccines as countermeasures against biological warfare agents.
<i>Vaccines, Plant Derived Vaccine Against Anthrax and Smallpox</i> Develop plant-based subunit vaccines against anthrax and smallpox as countermeasures against agents of biological warfare. Express both proposed vaccines in edible plants using a constitutive expression system based on transgenic plants. Express in spinach functionally important epitopes of the anthrax recombinant Protective Antigen (rPA) and the B5R protein of the smallpox virus, using a transient expression system based on plant virus vectors. Evaluate immunogenicity of plant-based vaccines in animal models.	<i>Vaccines, Plant Derived Vaccine Against Anthrax and Smallpox</i> - Developed plant-based subunit vaccines against anthrax and smallpox as countermeasures against agents of biological warfare. Expressed both proposed vaccines in edible plants using a constitutive expression system based on transgenic plants. Expressed in spinach functionally important epitopes of the anthrax recombinant Protective Antigen (rPA) and the B5R protein of the smallpox virus, using a transient expression system based on plant virus vectors. Evaluated immunogenicity of plant-based vaccines in animal models.

3.4.2.4 TB1 Future Targets

FY 2005 Targets	FY 2006 Targets
<i>Therapeutics, Bacterial</i> Evaluate efficacy of selected licensed and investigational products for efficacy in mice against bacterial threat agents. Maintain surveillance of products in the U.S. so that new products can be	<i>Therapeutics, Bacteria</i> Evaluate if cellular immune response against the F1-V fusion protein of plaque can be screened for potential therapeutics approaches, particularly through cytokine mediated pathways or expression of heat shock proteins.

FY 2005 Targets	FY 2006 Targets
evaluated for efficacy in vitro and in vivo. Initiate efficacy studies of IND antibiotics for inhalational anthrax in NHPs. Evaluate Heat Shock Proteins (HSPs) with candidate vaccines. Evaluate immunoglobulin therapies for bacterial threat agents.	
<i>Diagnostic Technologies</i> - Develop nucleic acid and immunoassays to detect identified threat agents in clinical samples. Perform research on diagnostic approaches to the early recognition of infections. Develop confirmatory tests for toxins. Pursue evaluation of systems compatible with future comprehensive integrated diagnostics. Direct research towards solving the technical problems associated with clinical sample preparation and rapid diagnostics. Evaluate new chemistries for the identification of biological warfare agents	<i>Diagnostic Technologies</i> - Expand nucleic acid and immunoassays for the detection of identified threat agents in clinical samples to additional agents/targets. Invest in improving existing assays, as new genomic data and techniques become available. Continue to pursue diagnostic approaches to the early recognition of infections and the evaluation of systems compatible with future comprehensive integrated diagnostics. Focus research on simplifying sample preparation techniques and evaluating rapid diagnostics platforms. Continue to evaluate new chemistries for the identification of biological warfare agents.
<i>Therapeutics, Toxin</i> Identify custom synthesis of structural analogs of lead compounds by high-throughput screening assays for toxins. Refine X-ray data for toxin-inhibitor co-crystal structures of most promising botulinum neurotoxin inhibitors. Perform computational chemistry studies to refine lead compound co-crystal structures. Perform test of lead compounds using in vivo model systems for assessment of therapeutic efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for toxins. Test FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo. Develop lead monoclonal antibody systems against toxins as passive immunotherapeutics in vivo.	<i>Therapeutics, Toxin</i> Develop surrogate endpoints of human clinical efficacy for toxins.
<i>Therapeutics, Viral</i> Develop high throughput in vitro drug screening assays and identify new molecular targets and develop assays by identification of a suitable target, cloning, expression and characterization of the target protein. Perform drug discovery assays to identify and test leading antivirals with in vitro assays. Identify compounds that demonstrate antiviral activity in small animal models and in vitro assays using authentic filoviruses and orthodox viruses. Identify potential mediators of shock or toxemia in appropriate animal models. Develop, characterize and evaluate the ability of monoclonal antibodies to viral specific proteins to neutralize the specific virus in vitro and in vivo and map monoclonal antibodies to distinct epitopes and to determine affinity and the importance of isotype. Develop appropriate small animal model to study Marburg virus infection.	<i>Therapeutics, Viral</i> Identify and test leading antivirals in appropriate animal models and worst-case scenarios such as viral challenge dose, route, and variation in viral challenge strain. Validate potential mediators of shock or toxemia and determine the basis for the treatment of shock or toxemia in appropriate animal models. Evaluate the utility of combining approaches that target different aspects of viral replication and/or disease pathogenesis. Standardize leading antivirals in appropriate animal models. Develop a strategic plan for licensure and manufacturing with lead compounds.
<i>Vaccine Research Support</i> Initiate project to develop a generic <i>Bacillus</i> vaccine, including identification of target antigens. Facilitate	<i>Vaccine Research Support</i> Developed construction of initial generic <i>Bacillus</i> vaccine candidates and begin initial immunogenecity

FY 2005 Targets	FY 2006 Targets
<p><i>and consolidate research efforts in <i>Brucella/Burkeholderia/Tularemia</i> to include identification of potential intracellular pathogen target antigens. Characterize novel virulence genes and gene products of selected bacterial threat agents to support discovery of new medical countermeasures. Identify new SEA/SEB structural determinants as potential immunogens to protect against multiple SE serotypes. Begin investigating the role of cytotoxic T cells in the higher animal model of filovirus infection. Expand development of animal models of aerosol infection with filoviruses. Determine the use of virus-like particles (VLP) and adenoviruses as antigen delivery platforms for vaccines against filoviruses.</i></p>	<p><i>studies. Identify and evaluate new target antigens for intracellular pathogens. Evaluate T-cell immune response against intracellular pathogens. Continue basic studies in anthrax and plague pathogenic mechanisms. Continue development of alternative delivery platform strategies for immunization. Continue the development of recombinant vaccine candidates for botulinum neurotoxins. Evaluate various platforms for compatibility with the V3526 vaccine candidate. Analyze Western and Eastern Equine Encephalitis (WEE/EEE) mutants with various engineered attenuating mutations. Evaluate additional target antigens for Ebola virus vaccine development. Continue to evaluate adenovirus-based immunization approaches for vaccination against filoviruses.</i></p>
<p><u><i>Multiagent Vaccines</i></u></p> <p>Identify bacterial multiagent vaccine target antigens. Clone and express chimeric vaccine constructs for multivalent toxin and bacterial vaccines by protein engineering. Initiate effort on anthrax-plague combined vaccine development. Establish new animal efficacy models. Explore genomics/proteomics-based high throughput approaches for potential vaccine target antigens. Explore use of Virus-Like Particles (VLP) for multiagent vaccine development. Evaluate DNA-based immunization against viral threat agents.</p>	<p><u><i>Multiagent Vaccines</i></u></p> <p>Continue to develop anthrax-plague vaccine, including third component. Evaluate specific combinations of target antigens and vaccine platforms such as adenovirus delivery vectors for vaccine development. Continue to explore genomics/proteomics-based high throughput approaches to identify potential vaccine target antigens. Evaluate use of Virus-Like Particles (VLP) for vaccine development. Continue to evaluate DNA-based immunization against viral threat agents.</p>
<p><u><i>Therapeutics, Viral</i></u></p> <p>Develop high throughput in vitro drug screening assays and identify new molecular targets and develop assays by identification of a suitable target, cloning, expression and characterization of the target protein. Perform drug discovery assays to identify and test leading antivirals with in vitro assays. Identify compounds that demonstrate antiviral activity in small animal models and in vitro assays using authentic filoviruses and orthopox viruses. Develop strategic plan for advanced development of compounds in regards to manufacturing and licensure. Identify potential mediators of shock or toxemia and determine the basis for the pathogenesis of shock or toxemia in appropriate animal models.</p> <p>Develop, characterize and evaluate the ability of monoclonal antibodies to viral specific proteins to neutralize the specific virus in vitro and in vivo and map protective monoclonal antibodies to distinct epitopes and to determine affinity and the importance of isotype.</p> <p>Develop appropriate small animal model to study Marburg virus infection.</p>	<p><u><i>Therapeutics, Viral</i></u></p> <p>Identify and test leading antivirals in appropriate animal models and worst-case scenarios such as viral challenge dose, route, and variation in viral challenge strain. Validate potential mediators of shock or toxemia and determine the basis for the treatment of shock or toxemia in appropriate animal models. Evaluate the utility of combining approaches that target different aspects of viral replication and/or disease pathogenesis. Standardize leading antivirals in appropriate animal models. Develop a strategic plan for licensure and manufacturing with lead compounds.</p>

3.4.2.5 Assessment of Medical Biological Defense Basic Research. Basic research efforts in FY04 and extensive research continues to be conducted in several research areas to include Bacterial Therapeutics, Diagnostic Technologies, Toxin Therapeutics, and Viral Therapeutics. These research efforts are intended to support several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies are being initiated in FY05,

in the areas of Vaccine Technology Development, Vaccine Research Support, and Multivalent Vaccines.

3.4.3 Medical Chemical Defense Basic Research (Project TC1)

This project emphasizes understanding of the basic action mechanisms of nerve, blister (vesicating), blood, and respiratory agents. Basic studies are performed to delineate mechanisms and sites of action of identified and emerging chemical threats to generate required information for initial design and synthesis of medical countermeasures. In addition, these studies are further designed to maintain and extend a science base. Categories for this project include science and technology program areas (Nerve Agent Defense, Vesicant Agent Defense and Chemical Warfare Agent (CWA) Defense) and directed research efforts (Low Level CWA Exposure and Non-Traditional Agents).

3.4.3.1 TC1 Performance Goal (Outcome). The goal of medical chemical defense basic research is to increase scientific understanding of the mechanisms, processes, and effects of chemical warfare (CW) agents and the science involved in the detection, protection against, and decontamination of CW agents.

3.4.3.2 TC1 Outcome Measure

TC1 is minimally effective when	TC1 is successful when
<ul style="list-style-type: none"> The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> Toxicology of exposures to low levels of CW agents, Pretreatments for chemical agent exposures, Therapeutics for chemical agent exposures, Non-traditional agents. The results of research are published in peer-reviewed journals or presented at scientific conferences Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.3.3 TC1 Actual and Planned Performance:

FY 2004 Targets	Actual Performance
<u>Nerve Agent Defense, Neuroprotection</u> Evaluate drug treatment strategies and combinations of therapies for nerve agent-induced seizures.	<u>Nerve Agent Defense, Neuroprotection</u> Evaluate drug treatment strategies and combinations of therapies for nerve agent-induced seizures.
<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Identify mechanism of action of vesicant pretreatment compounds. Determine effects of sulfur mustard (HD) on cell structure using multiphoton laser scanning microscopy. Analyze in vitro effects of HD on cellular energy metabolism. Study in vitro biochemical changes induced by HD.	<u>Vesicant Agent Defense, Vesicant Medical Countermeasure</u> Identify mechanism of action of vesicant pretreatment compounds. Determine effects of sulfur mustard (HD) on cell structure using multiphoton laser scanning microscopy. Analyze in vitro effects of HD on cellular energy metabolism. Study in vitro biochemical changes induced by HD.
<u>Chemical Warfare Agent Defense, Inhalation Therapeutics</u> Investigate enzymatic targets of HD. Conduct a dose-response assessment of early acute lung injury in rodents administered intravascular HD. Determine the biochemical effects in male and female guinea pigs following exposure to chemical warfare agents.	<u>Chemical Warfare Agent Defense, Inhalation Therapeutics</u> Investigate enzymatic targets of HD. Conduct a dose-response assessment of early acute lung injury in rodents administered intravascular HD. Determine the biochemical effects in male and female guinea pigs following exposure to chemical warfare agents.

FY 2004 Targets	Actual Performance
<u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Identify molecular intracellular proteomic changes following HD exposure.	<u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Identify molecular intracellular proteomic changes following HD exposure.
<u><i>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</i></u> Identify biomarker(s) to indicate low level chemical exposure. Continue studies of neurotoxic effects of low dose chemical agent exposure. Examine potential for immunological deficits following nerve agent exposures. Identify potential medical countermeasures for low level chemical warfare nerve agent and HD exposure	<u><i>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</i></u> Identify biomarker(s) to indicate low level chemical exposure. Continue studies of neurotoxic effects of low dose chemical agent exposure. Examine potential for immunological deficits following nerve agent exposures. Identify potential medical countermeasures for low level chemical warfare nerve agent and HD exposure.
<u><i>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</i></u> Investigate changes to pulmonary airway resistance and permeability of Pulmonary microvessels induced by exposure to various concentrations of platelet activating factor (PAF). Identify changes in the global gene expression profile of cultured human epidermal keratinocytes (HEK) in response to NTA exposure using DNA microarrays and genomics techniques to aid in considering strategies leading to medical countermeasures.	<u><i>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</i></u> Investigate changes to pulmonary airway resistance and permeability of pulmonary microvessels induced by exposure to various concentrations of platelet activating factor (PAF). Identify changes in the global gene expression profile of cultured human epidermal keratinocytes (HEK) in response to NTA exposure using DNA microarrays and genomics techniques to aid in considering strategies leading to medical countermeasures.

3.4.3.4 TC1 Future Targets

FY 2005 Targets	FY 2006 Targets
<u><i>Nerve Agent Defense, Neuroprotection</i></u> Test putative neuroprotectants in at least one and possibly more than one animal species.	<u><i>Nerve Agent Defense, Neuroprotection</i></u> Compare these events to what is known of mechanisms of cell death in other forms of status epilepticus and to stroke. As candidates emerge from Objective A, priority may be given to studies that attempt to characterize the mechanism of protection seen with successful candidates. The mechanisms with various classes of candidates may differ.
<u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Characterize pathophysiological endpoints. Continue elucidation of pathophysiological schema. Identify points in schema for potential pharmaceutical intervention.	<u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Continue to explore purification and delivery strategies of vesicant pretreatments. Continue to analyze in vitro effects of HD on cellular energy metabolism. Continue to study in vitro biochemical changes induced by HD.
<u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Identify and solicit for scientifically plausible animal and non-animal exposure models to investigate mechanisms of toxicity on pulmonary related function and to establish in-house and collaborative research programs within the confines of the approach.	<u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Initiate experimentation in the areas of interest (stated above) by establishing exposure/effects models from in vitro to in vivo systems by addressing a commonality of response/effects, i.e., identify a common response effect regardless of inhaled toxicant.
<u><i>Diagnostic Technologies</i></u> Perform basic research experiments aimed at developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Conduct experiments focusing on detecting sulfur mustard exposure by cleavage of adducts formed with blood proteins. Assess lab based Ellman cholinesterase assay for automation and	<u><i>Diagnostic Technologies</i></u> Continue basic research experiments aimed at developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Focus on developing assays for detecting sulfur mustard exposure. Develop automation/high throughput strategy for cholinesterase assay. Continue development of alternate

FY 2005 Targets	FY 2006 Targets
increased throughput. Explore alternate sample collection/extraction technology to standard hydrolysis product assays.	sample collection/extraction technology. Initiate literature review to assess the development of a genomics-based diagnostic screening test for chemical warfare agent exposure.
<u>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</u> Examine multiple biomarkers as confirmatory for low level chemical exposure. Study possible immunological deficit following low level chemical nerve agent exposure. Examine physiological parameters that may alter sensitivity to low level CWAs. Identify potential medical countermeasures for low level CWA exposures.	<u>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</u> Complete studies of medical countermeasures that minimize the effects of low level chemical exposure. Determine the effects of repeated exposure to chemical agents on CNS gene and protein expression in rodents.
<u>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</u> Compare the direct effects of PAF on smooth muscle, hematic constituents, and lung to determine role in toxicity. Continue to identify changes in the global gene expression profile of cultured HEK exposed to NTAs using DNA microarrays and genomic techniques to aid in considering strategies leading to medical countermeasures.	<u>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</u> Study the oxidative metabolism of non-traditional convulsive agents. Study the pathophysiology of more classes of NTA's

3.4.3.5 Assessment of Chemical Biological Defense Basic Research. Basic research efforts in FY04 for project TC1 were effective. The program completed most major targets. These research areas are intended to support several major operational goals detailed in Section 2 of the performance plan. The program intends to continue work in all identified areas in FY05.

3.5 APPLIED RESEARCH (PROGRAM ELEMENT 0602384BP)

The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a CB attack and enables U.S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatment, and therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the non-medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. This program also provides for conduct of applied research in the areas of real-time sensing and immediate biological countermeasures. This PE also provides concept and technology demonstrations of new system concepts that will shape the development for environmental monitoring, medical surveillance, and data mining/fusion/analysis subsystems. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP). This project includes non-system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

3.5.1 Chemical and Biological Defense Applied Research (Project CB2)

This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from threat CB agents in the areas of detection, identification and warning, contamination avoidance via reconnaissance, individual and collective protection, and

decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and NBC survivability. Of special interest are two Defense Technology Objectives described as follows: (1) The fate of CW agents following deposition onto natural and man-made materials found in operation environments including battlefields and air bases and (2) toxicological effects resulting from low-level exposure to CW agents, e.g., less than 0.1 EC₅₀, as well as the relationships between concentration and total exposure as measured by the product of concentration and time. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The DTOs provide a means to shape the development of selected technologies within this project.

3.5.1.1 CB2 Performance Goal (Outcome). The goal of the CB defense non-medical applied research program is to increase scientific understanding of the mechanisms and processes involved in chemical and biological warfare (CBW) agents and potential applications of this information for the development of advanced technologies for the detection, protection against, and decontamination of CBW agents.

3.5.1.2 CB2 Outcome Measure

CB2 is minimally effective when	CB2 is successful when
<ul style="list-style-type: none"> The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> – biosensors for point detection and early warning, – critical reagents for biological agent detection & identification, – aerosol sciences, – threat agents, – agent dispersion and fate modeling, – advanced materials for individual protection, – advanced methods and materials for decontamination, – chemistry and toxicology of bioactive compounds, – man portable thin film technology, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – new detection technologies. The results of research are published in peer-reviewed journals or presented at scientific conferences Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development All DTOs are rated GREEN by the TARA Panel.

3.5.1.3 Metric Description. The metric for CB2 is described in Section 3.2.1.1. Applied research also includes several specific DTOs, which are described in Chapter 2 and Annexes A–D of the 2005 *DoD CB Defense Program Annual Report to Congress*.

3.5.1.4 CB2 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u><i>Advanced Adsorbents for Protection Applications (DTO CB08)</i></u> Complete validation of single-pass and regenerative filtration adsorption models. Complete performance verification of adsorbents for use in NBC filtration systems with emphasis on regenerative materials. Selected adsorbent beds will undergo performance verification testing to fully assess the performance	<u><i>Advanced Adsorbents for Protection Applications (DTO CB08)</i></u> Completed fundamental single-pass and regenerative filtration adsorption models. Completed performance verification of new adsorbent formulations for use in NBC filtration systems. Evaluations considered adsorbent bed performance under a wide range of agent challenge concentration scenarios and environmental

FY2004 Targets	Actual Performance
constraints expected in the host filter system. These evaluations will consider adsorbent bed performance under a wide range of agent challenge concentration scenarios and environmental conditions. Selection of the best adsorbent bed composition for regenerative filtration application will be made. If temperature swing adsorption and pressure swing adsorption are both considered viable regenerative filter technologies, at least two different adsorbent bed compositions will be selected.	conditions. Selection of the best adsorbent bed compositions were made. Completed DTO and transitioned efforts into the Joint Service General Purpose Mask (JSGPM) and Joint Collective Equipment Program (JCEP) programs.
<u><i>Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20)</i></u> - Continue develop of new taggant chemistry for multi-agent, multiplexing PCR assays. Complete redesign and initiate modifications to the breadboard.	
<u><i>Stand-off Biological Aerosol Detection (DTO CB35)</i></u> Complete construction and characterization of breadboards to demonstrate the capability to detect and discriminate biological and non-biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km.	<u><i>Stand-off Biological Aerosol Detection (DTO CB35)</i></u> Completed construction and laboratory characterization of breadboards to demonstrate the capability to detect and discriminate biological and non-biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km. This DTO supported the Joint Biological Stand-off Detection Systems (JBSDS) that addressed Baseline Capability Assessment for Biological Stand-Off Detection - Limited developmental capability; priority number one.
<u><i>End-of-Service-Life Indicators for NBC Mask Filters (DTO CB36)</i></u> Fabricate and conduct demonstration testing of ESLI filter concept models to verify ESLI is a reliable indicator of gas life depletion for key target agents (i.e., GB, HD, CK, AC and CG). Assessments will include determining the effects of common environmental factors (heat and humidity) that may impact ESLI performance and evaluating the effects of long-term storage.	<u><i>End-of-Service-Life Indicators for NBC Mask Filters (DTO CB36)</i></u> Continued fabrication and demonstration testing of ESLI filter concept models to verify ESLI is a reliable indicator of gas life depletion for key target agents (i.e., GB, HD, CK, AC and CG). Continued efforts to determine the effects of common environmental factors (i.e., heat and humidity) that may impact ESLI performance and evaluated the effects of long term storage. This DTO supported several protective equipment (mask) programs that addressed Baseline Capability for Respiratory and Ocular Protection - Limited TIC protection; priority number 19.
<u><i>Predictive Modeling - Agent Fate (DTO CB42)</i></u> Develop evaporation and liquid contact models and integrate into the Joint Effects Model (JEM). Expand surface evaporation database to include all agent/simulant data from large area surfaces and continually add data generated from the Agent Fate program. Expand the features and accuracy of CHEMRAT by including current data from the Agent Fate program to support Operation Iraqi Freedom and future military operations. Calibrate VLSTRACK by adjusting parameters relevant to secondary evaporation to provide better vapor hazard and liquid persistence estimates. Enhance SRFSIM and SURFIT assessment tools by including secondary evaporation methodology from the Hazard Prediction Assessment Capability model (HPAC). Perform sensitivity analysis of HPAC 4.0.3 secondary evaporation methodology.	<u><i>Environmental Fate of Agent (DTO CB42) - Predictive Modeling</i></u> Developed evaporation and liquid contact models and integrated into the Joint Effects Model (JEM). Expanded surface evaporation database to include all agent/simulant data from large area surfaces and continually added data generated from the Agent Fate program. Expanded the features and accuracy of CHEMRAT by including current data from the Agent Fate program to support Operation Iraqi Freedom and future military operations. Calibrated VLSTRACK by adjusting parameters relevant to secondary evaporation to provide better vapor hazard and liquid persistence estimates. Enhanced SRFSIM and SURFIT assessment tools by including secondary evaporation methodology from the Hazard Prediction Assessment Capability model (HPAC). Performed sensitivity analysis of HPAC 4.0.3 secondary evaporation methodology. This DTO addressed Baseline Capability Assessment for

FY2004 Targets	Actual Performance
	Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis – Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.
<u>Methodology Development - Agent Fate (DTO CB42)</u> Determine degradation products of agents on surfaces of interest such as concrete. Using HS-SPME, measure and correlate VX, GD, and HD on Czech concrete vs. NIST standard concrete. Using HS-SPME, measure VX, GD, and HD on asphalt, soil and metal/glass at three humidity levels and compare single vs. multiple droplets surface contamination. Initiate HS-SPME measurements of NTAs. Initiate soil methodology development and determine sorption and fate of GD on dry sand and its response to simulated rainfall. Determine the fate of RVX, NTA, and HD on concrete by NMR and add GD if schedule allows.	<u>Environmental Fate of Agents (DTO CB42) - Methodology Development</u> Determined degradation products of agents on surfaces of interest such as concrete. Using HS-SPME, measured and correlated VX, GD, and HD on Czech concrete vs. NIST standard concrete. Using HS-SPME, measured VX, GD, and HD on asphalt, soil and metal/glass at three humidity levels and compared single vs. multiple droplets surface contamination. Initiated HS-SPME measurements of NTAs. Initiated soil methodology development and determined sorption and fate of GD on dry sand and its response to simulated rainfall. Determined the fate of RVX, NTA, and HD on concrete by Nuclear Magnetic Resonance (NMR).
<u>Lab-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</u> Measure surface evaporation of HD and GD on asphalt in lab wind tunnels. Measure surface evaporation of HD and VX on concrete in lab wind tunnels. Initiate investigations of VX and NTAs on asphalt. Initiate surface evaporation of thickened GD, VX, and HD on concrete and asphalt. Complete fabrication and certification of large scale wind tunnel in the UK. Field Testing Methodology will be reviewed to prepare for resumption of outdoor testing in FY05. Continue wind tunnel testing of HD, GD, and VX on asphalt, sand, and vegetation.	<u>Environmental Fate of Agents (DTO CB42) - Large-Scale and Lab-Scale Wind Tunnel Studies</u> Initiated investigations of VX and NTAs on asphalt. Initiated surface evaporation of thickened GD, VX, and HD on concrete and asphalt. Measured surface evaporation of HD and GD on asphalt in lab wind tunnels. Completed fabrication and certification of large scalewind tunnel in the UK. Reviewed Field Testing Methodology to prepare for resumption of outdoor testing in FY05. Continued wind tunnel testing of HD, GD, and VX on asphalt, sand, and vegetation. This DTO supported Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five, Battle Space Analysis - Lack of analysis tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.
<u>Chemical and Biological Warfare Effects on Operations (DTO-CB43)</u> - Complete and demonstrate initial operational capability of APOD module. Conduct independent Validation and Verification (V&V) of fighter base module. Initiate development and testing of Sea Port of Debarkation (SPOD) module.	<u>Chemical and Biological Warfare Effects on Operations (DTO CB43)</u> Tested and finalized APOD and SPOD representation. Populated SPOD representation. Completed Joint Operational Effects Federation (JOEF) demonstration. Completed independent validation and verification on core model. This DTO supported Baseline Capability Assessment for Battle Space Management - Lack of automated decision tools; priority number eight and

FY2004 Targets	Actual Performance
<u>Decontamination - Oxidative Formulation (DTO CB44)</u> Initiate chamber testing over operational temperature range, finish material compatibility testing and formulate peroxycarbonate and peracid candidates into a dry powder and/or concentrated liquid. Finalize formulation of newly added oxidative approaches and conduct material compatibility and agent testing.	<u>Decontamination - Oxidative Formulation (DTO CB44)</u> Initiated chamber testing over operational temperature range, finished material compatibility testing and formulated peroxycarbonate and peracid candidates into a dry powder and/or concentrated liquid. Finalized formulation of newly added oxidative approaches and conducted material compatibility and agent testing. This DTO supported the Joint Tactical Decontamination Systems (JSTDs) and addressed Baseline Capability Assessment for Equipment Decon - Decontaminants and applicators degrade equipment; priority number 18, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, and Fixed Site Decontamination - Applicators degrade equipment, facilities, and material; priority number 34.
<u>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</u> Demonstrate ability to produce materials employing self detoxification chemistries for G-agents, VX, and HD by commercial electrospinning. Demonstrate improved reactivities for hyperbranched surface migrating compounds. Demonstrate agent deactivation chemistry of fiber bound catalysts through solution and vapor challenge testing for a target reactivity level of 2 mg agent/cm ² /day. Demonstrate effectiveness of scaled up N-halamine treated materials against significant biological. Demonstrate nanoparticle reactivities in excess of 2 mg agent/cm ² /day in both fiber and coating form. Downselect most reactive, cost effective nanoparticle compositions and optimize those materials for reactivity rates and range of materials they detoxify	<u>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</u> Demonstrated ability to produce materials employing self detoxification chemistries for G-nerve agents, VX, and HD blister by commercial electrospinning. Demonstrated improved reaction rates for hyperbranched surface migrating compounds. Demonstrated agent deactivation chemistry of fiber bound catalysts through solution and vapor challenge testing for a target reactivity level of 1 mg agent/cm ² /day. Demonstrated effectiveness of scaled up N-halamine treated materials against significant biological challenges. Demonstrated nanoparticle reaction rates in excess of 2 mg agent/cm ² /day in both fiber and coating form. Downselected most reactive, cost effective nanoparticle compositions and optimize those materials for reactivity rates and range of materials they detoxify. This DTO supported Joint Expeditionary Collective Protection (JECP) program which addressed Baseline Capability Assessment (BCA) Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary COLPRO - Correct quantity shortfalls; priority number 25. The DTO also supported the current Joint Service Lightweight Integrated Suit Technology (JSLIST) program.
<u>Lightweight Integrated CB Detection (DTO CB50)</u> Complete the population of the technical parameter database. Transition the analysis of alternatives to advance development for downselection for best technology to meet the requirements of the Joint Modular CB Detector.	<u>Lightweight Integrated CB Detection (DTO CB50)</u> Completed population of the technical parameter database. Transitioned the Analysis of Alternative (AoA) to advanced development for selection of best technology to meet the requirements of the Joint Modular CB Detector. This DTO addressed Baseline Capability Assessment for Integrated Early Warning - Limited sensor interface, priority number three and Integrated Early Warning - Lack of selective alarm; priority number four.
<u>Low Level Operational Toxicology Studies (DTO CB51)</u> Complete initial inhalation studies for the nerve agents	<u>Low-Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO CB51)</u>

FY2004 Targets	Actual Performance
GF and VX. Deliver a refined operational human health risk assessment for those agents suitable for integration into Operational Risk Management processes used by commanders in military settings. Evaluate the utility of diverse non-human data for extrapolation to human conditions based on a common dosimetric.	Low Level Operational Toxicology Studies (- Completed initial inhalation studies for the nerve agents GF and VX. Delivered a refined operational human health risk assessment for those agents suitable for integration into Operational Risk Management processes used by commanders in military settings. Evaluated the utility of diverse non-human data for extrapolation to human conditions based on a common dosimetric. This DTO addressed Baseline Capability Assessment for Chemical Agent Stand-Off Detection - Lack of detect and identify capability; priority number 10, Chemical Agent Point Detection - Lack of small (size, weight) and accurate detectors; priority number 20, Percutaneous Protection - Limited dusty agent protection; priority number 26, and Chemical Agent Point Detect - Lack of detection for solids and liquids; priority number 31.
<u><i>Detection of CB Contamination on Surfaces (DTO CB52)</i></u> Collect data on three surfaces for four surety agents using laser enhanced Raman spectroscopy to detect the presence of the chemical agents. Effort reduced due to FY04 funding adjustments.	<u><i>Detection of CB Contamination on Surfaces (DTO CB52)</i></u> Initiated data collection on three surfaces for four surety agents using laser enhanced Raman spectroscopy to detect the presence of the chemical agents. This DTO supported the Baseline Capability Assessment for Chemical Point Detection - Inability to detect NTAs and TICs; priority number 33.
<u><i>Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</i></u> Complete the development a 30-Hz frame rate, 64-pixel Fourier transform infrared (FTIR) hyperspectral imager (TurboFT). Continue the development of AIRIS. Characterize the sensor performance on the TurboFT for downselection of technology in FY06. Initiated development of off-line algorithms and signal processing techniques.	<u><i>Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</i></u> Completed the development a 30-Hz frame rate, 64-pixel Fourier transform infrared (FTIR) hyperspectral imager (TurboFT). Continued the development of AIRIS. Continued characterization of the sensor performance on the TurboFT for downselection of technology in FY06. Initiated development of off-line algorithms and signal processing techniques. This DTO supported the Joint Service Light Nuclear-Biological-Chemical Reconnaissance System (JSLNCRS) and STRYKER programs and addressed Baseline Capability Assessment NBC Reconnaissance - Lack of sensor integration; priority number 28.
<u><i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i></u> Transition advanced predictive capabilities (MESO) to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. Investigate availability of high altitude dispersion model in support of JEM Block II	<u><i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i></u> Investigated availability of high altitude dispersion model in support of Joint Effects Model (JEM) Program. Transitioned advanced predictive capabilities (MESO) to JEM program. Further enhanced the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. This DTO supported Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of analysis tools; priority number six.
<u><i>Point Detection, Biological Identification</i></u> Complete development and demonstration of Force Discrimination Assay (FDA). Complete development and testing automation of chip-based phylogenetic	<u><i>Point Detection, Biological Identification</i></u> Completed development and demonstration of Force Discrimination Assay (FDA). Completed development and testing automation of chip-based phylogenetic

FY2004 Targets	Actual Performance
analysis of biological materials. Identify engineering/manufacturing issues for the transition of quantum dot technology to the Critical Reagent Program for application to enhance antibody ticket technology for improved stability and sensitivity. Continue development of database for protein markers from biological agents for mass spectroscopy based systems.	analysis of biological materials. Identified engineering/manufacturing issues for the transition of quantum dot technology to the Critical Reagent Program for application to enhance antibody ticket technology for improved stability and sensitivity. Completed mapping of spore protein markers from biological agents for mass spectroscopy based systems.
<u>Point Detection, Integrated CB</u> Continue exploration of novel concepts in small, combined chemical and biological sensors. Continue development of millimeter wave spectroscopy.	<u>Point Detection, Integrated CB</u> Completed exploration of novel concepts in small, combined chemical and biological sensors. Continued development of millimeter wave spectroscopy.
<u>Laser Induced Surface Analysis (LISA) Prototype</u> Construct and demonstrate a laser enhanced Raman system that can detect the presence of chemical agent on surfaces at a contamination level of 0.5 g/m ² and suitable for integration into a recon vehicle to demonstrate on the move capability.	<u>Laser Induced Surface Analysis (LISA) Prototype</u> Constructed and demonstrated a laser enhanced Raman system that can detect the presence of chemical agent on surfaces at a contamination level of 0.5 g/m ² and suitable for integration into a recon vehicle to demonstrate on the move capability.
<u>Bioinformatics</u> Continue creating tailored approaches to extract and rapidly analyze biological data to enhance the study of chemical and biological threat agent effects.	<u>Bioinformatics</u> Continued creating tailored approaches to extract and rapidly analyze biological data to enhance the study of chemical and biological threat agent effects.
<u>Collective Protection, Filtration</u> Characterize constraints of mature candidate adsorbent compositions against a wide range of TIC and CWA including aging, chemical reaction regeneration cycles, relative humidity, temperature, and material compatibility. Optimize regenerative process (including, temperature, pressure, ECS, cycle time) using verified candidate adsorbent materials. This task will mature the technology for future consideration as an advanced technology demonstrator. Complete literature review and database of unit processes for developing hybrid air purification systems. Downselect anti-microbial aerosol/particulate filter media, complete initial testing and develop enhanced prototype.	<u>Collective Protection, Filtration</u> Characterized constraints of mature candidate adsorbent compositions against a wide range of TIC and CWA including aging, chemical reaction regeneration cycles, relative humidity, temperature, and material compatibility. Optimized regenerative process for temperature, pressure, ECS, cycle time to verify candidate adsorbent materials. Developed regenerative technology demonstrator and obtaining performance data. Conducted literature review and initiated database development of unit processes for developing advance air purification systems. Tested anti-microbial aerosol/particulate filter media and develop enhanced prototype. Transitioned effort to 6.3.
<u>Collective Protection, Shelters</u> Continue development and testing of advanced CB shelter materials and prototype shelter system components (shell, liner, support, airlocks, seams and seals). Identify and test optimal chemistries for self-decontaminating shelter materials and applications. Conduct airflow modeling of airlock and contamination control area configurations to optimize designs to reduce dwell time, increase entry/exit rate, and facilitate dual entry and exit of personnel, patients and supplies.	<u>Collective Protection, Shelters</u> Continued development and testing of advanced CB shelter materials and prototype shelter system components (shell, liner, support, airlocks, seams and seals). Continued to identify and test chemistries for self-decontaminating shelter materials and applications. Continued airflow modeling of airlock configurations to optimize designs to reduce dwell time, increase entry/exit rate, and facilitate dual entry and exit of personnel, patients and supplies.
<u>Individual Protection, Masks</u> Refine advanced mask system concepts using actual technologies to the maximum extent possible. Optimize candidate mask sealing options and assess antifogging and moisture control technologies. Prepare human use bio-aerosol protection factor assessment protocol, establish and validate test procedures, and conduct human PF study with monodisperse inert aerosols.	<u>Individual Protection, Masks</u> Refined advanced mask system concepts using actual technologies to the maximum extent possible. Optimized candidate mask sealing options and assessed anti-fogging and moisture control technologies. Prepared human use bio-aerosol protection factor assessment protocol, established and validated test procedures, and conducted human PF study with

FY2004 Targets	Actual Performance
<u>Decontamination, Sensitive Equipment</u> Complete evaluation of man portable approaches for the cleaning of small sensitive surfaces for use in the interior of vehicles and aircraft.	monodisperse inert aerosols. <u>Decontamination, Sensitive Equipment</u> Evaluated portable approaches for the cleaning of small sensitive surfaces for use in the interior of vehicles and aircraft. Conducted a cold weather thermal decontamination study for interior spaces.
<u>Decontamination, Solid Phase Chemistry</u> Initiate evaluation of oxidatively enhanced nanoparticles as reactive sorbents for both chemical and biological agent decontamination.	<u>Decontamination, Solid Phase Chemistry</u> Evaluated enhanced oxidative nanoparticles as reactive sorbents for both chemical and biological agent decontamination. Conducted a study to determine why nanoscale materials show no advantage over conventional microscale solids in sorbent operations.
<u>Aerosol Technology</u> Experimentally and by CFD analysis, initiate investigations of inlets to facilitate aerosol collection in high air speed conditions. Continue experimental and CFD studies of microHEPA, electrostatic collector, mini-slit and other low power aerosol collection devices. Fabricate and test breadboard aerosol collector capable of low temperature operation. Characterize and evaluate emerging collectors and collection technology. Develop new aerosol generation and analysis techniques including methodology development to generate suitable chemical simulant aerosol challenges. Complete enhanced lidar aerosol test cell to support stand-off detection tests. Continue development of new methodology for quantifying biological aerosols captured in collector/concentrator characterization experiments.	<u>Aerosol Technology</u> Initiated investigations of inlets to facilitate aerosol collection in high air speed conditions. Continued experimental studies of microHEPA, electrostatic collector, mini-slit and other low power aerosol collection devices. Fabricated and tested breadboard aerosol collector capable of low temperature operation. Characterized and evaluated emerging collectors and collection technology. Developed new aerosol generation and analysis techniques including methodology development to generate suitable chemical simulant aerosol challenges. Completed enhanced LIDAR aerosol test cell to support stand-off detection tests. Continued development of new methodology for quantifying biological aerosols captured in collector/concentrator characterization experiments.
<u>Threat Agents and Simulants</u> Continue efforts to determine and validate new synthesis targets. Discontinue quantum chemistry research due to funding reductions. Continue to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CWA simulants. Complete investigations of physical and decontamination properties of <i>B. anthracis</i> . Investigate physical properties and decontamination properties of <i>E. herbicola</i> and baculovirus. Continue update of classified ASK databases and provide to CBIAC when completed. Continue effort to identify and validate non-pathogenic antigen mimics. Complete methodology development for assessing inhalation toxicity of non-traditional agents.	<u>Threat Agents and Simulants</u> Continued efforts to determine and validate new synthesis targets. Continued to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CWA simulants. Completed investigations of physical and decontamination properties of <i>B. anthracis</i> . Investigated physical properties and decontamination properties of <i>E. herbicola</i> and baculovirus. Continued update of classified Agent Simulant Knowledge (ASK) databases and provide to Chemical and Biological Information Analysis Center (CBIAC) when completed. Continued effort to identify and validate non-pathogenic antigen mimics. Completed methodology development for assessing inhalation toxicity of non-traditional agents.
<u>Threat Agents</u> Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of <i>Y. pestis</i> . Continue characterization of fundamental properties of a viral family and initiate characterization on a second viral family selected by biodefense priorities. Complete validation studies on simulant BG	<u>Threat Agents</u> Continued to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continued to characterize fundamental properties of <i>Y. pestis</i> . Continued characterization of fundamental properties of a viral family and initiated characterization on a second viral family selected by biodefense priorities. Completed validation studies on

FY2004 Targets	Actual Performance
spores and continue improvement of <i>Erwinia herbicola</i> antigenicity, exploration of novel "peptide-based" bio simulants, and research on a new viral simulant. Continue development of an agent simulant knowledge base technical information system with emphasis on completion of environmental database and initiate the collection and quality assessment of classified and incapacitating agent data. Load bioinformatics database with fundamental non-medical properties.	simulant BG spores and continue improvement of <i>Erwinia herbicola</i> antigenicity, exploration of novel "peptide-based" bio simulants, and research on a new viral simulant. Continued development of an agent simulant knowledge base technical information system with emphasis on completion of environmental database and initiated the collection and quality assessment of classified and incapacitating agent data. Loaded bioinformatics database with fundamental non-medical properties.
<u><i>Biological Agent Fate</i></u> Initiate an accelerated all-source compilation and analysis of existing literature data that addresses the persistence (viability) of biological warfare agents released into the operational environment. Conduct a state of current research expert workshop in conjunction with NATO/allied investigators to document research efforts in the fate of biological agents. Deliver a documented assessment of identified data gaps and produce a targeted Defense Technology Objective (DTO) research program.	<u><i>Biological Agent Fate</i></u> Initiated an accelerated all-source compilation and analysis of existing literature data that addresses the persistence (viability) of biological warfare agents released into the operational environment. Conducted a state of current research expert workshop in conjunction with NATO/allied investigators to document research efforts in the fate of biological agents. Delivered a documented assessment of identified data gaps and produced a targeted Defense Technology Objective (DTO) research program.
<u><i>Planning, Training and Analysis</i></u> Test and finalize APOD and SPOD representation. Define Contamination Avoidance for Seaports of Debarkation (CASPOD) data requirements. Populate SPOD representation. Support Joint Operational Effects Federation (JOEF) Block I demonstration. Perform independent validation and verification on core model.	
<u><i>Simulation Based Acquisition</i></u> Develop support tools for future acquisition decisions that would emerge from a study of CBDP requirements. Identify user base from within the CBDP. Begin prototype tool design efforts.	<u><i>Simulation Based Acquisition</i></u> Developed support tools for future acquisition decisions that would emerge from a study of CBDP requirements. Identified user base from within the CBDP. Initiated prototype tool design efforts.
<u><i>Battle Management</i></u> Initiate efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses under the auspices of Joint Warning and Reporting Network (JWARN) program requirements in concert with the C4ISR architecture.	<u><i>Battle Space Management</i></u> Continued efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses under the auspices of Joint Warning and Reporting Network (JWARN) program requirements in concert with the C4ISR architecture.
<u><i>Automated Lipid Phase Detection of Toxic Compounds</i></u> Automated lipid phase detection of toxic compounds program is being baselined.	<u><i>Automated Lipid Phase Detection of Toxic Compounds</i></u> Automated lipid phase detection of toxic compounds program is being baselined.
<u><i>Bioinformatics Network</i></u> Create linkages which interactively approach the extraction of rapid analysis of biological data.	<u><i>Bioinformatics Network</i></u> Created linkages which interactively approach the extraction of rapid analysis of biological data.
<u><i>Bioinformatics Equipment</i></u> Explore technologies for bioinformatics equipment.	<u><i>Bioinformatics Equipment</i></u> Explored technologies for bioinformatics equipment.
<u><i>Early Warning and Detection Program</i></u> Explore technologies for early warning and detection.	<u><i>Early Warning and Detection Program</i></u> Explored technologies for early warning and detection.
<u><i>LSH-SAW Biosensor</i></u> Investigate acoustic wave technology for biosensors.	<u><i>LSH-SAW Biosensor</i></u> Investigated acoustic wave technology for biosensors.
<u><i>Detection of Chemical, Biological and Pollutant Agents in Water</i></u> Continue technology development to detect CB and	<u><i>Detection of Chemical, Biological and Pollutant Agents in Water</i></u> Continued technology development to detect CB and

FY2004 Targets	Actual Performance
pollutant agents in potable water sources.	pollutant agents in potable water sources.
<u>Atmospheric Plasma for Bio Defense Decon</u> Investigate technologies for atmospheric plasma for biological defense decontamination.	<u>Atmospheric Plasma for Bio Defense Decon</u> Investigated technologies for atmospheric plasma for biological defense decontamination.
<u>Rapid Decontamination System for Nerve Agents</u> Explore technologies for rapid decontamination system for nerve agents.	<u>Rapid Decontamination System for Nerve Agents</u> Explored technologies for rapid decontamination system for nerve agents.
<u>Remote Optical Sensing Program</u> Explore technologies for remote optical sensing.	<u>Remote Optical Sensing Program</u> Explored technologies for remote optical sensing.
<u>Consortium for Countermeasures for Biological Threats</u> Develop multiple technologies and implementations to counter the threat of attack using biological threat agents against civilian and military populations.	<u>Consortium for Countermeasures for Biological Threats</u> Developed multiple technologies and implementations to counter the threat of attack using biological threat agents against civilian and military populations.
	<u>Global Pathogen Portal</u> Developed tools for creating, acquiring, and analyzing molecular level biological data.
<u>Center for Information Assurance Security</u> Investigate technologies for information assurance security.	<u>Center for Information Assurance Security</u> Funding to be withdrawn by OSD(C).
<u>GMU Center for Bio Defense</u> George Mason University Center for biological defense program being baselined.	
<u>Long Range Biometric Target ID System</u> Explore technologies for a long range biometric target identification system.	
<u>Air Containment Monitoring System</u> Continue development of systems for contained air monitoring for chemical agents.	<u>Air Containment Monitoring System</u> Continued development of systems for contained air monitoring for chemical agents

3.5.1.5 CB2 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>Stand-off Biological Aerosol Detection (DTO CB35)</u> Evaluate breadboards in field environments to detect and discriminate (biological vs non-biological) biological and chemical agents at concentration of 1,000 ACPLA at a range of 1km. Initiate feasibility studies to enhanced false alarm of one per week and to operate during daytime. This DTO supports the Joint Biological Stand-Off Detection Systems (JBSDS) that addresses Baseline Capability Assessment for BiologicalStand-Off Detection - Limited developmental capability; priority number one.	<u>Stand-off Biological Aerosol Detection (DTO CB35)</u> Demonstrate the optimized system performance to detect and discriminate biological agents with at least a sensitivity of 1000 agent containing particles per liter of air (ACPLA) at a range of 1 Km with an objective false alarm rate no more than one per week in both daytime and nighttime operations. Evaluate the feasibility of the demonstrated technology to meet chemical stand-off detection requirements. This DTO supports the Joint Biological Stand-Off Detection Systems (JBSDS) that addresses Baseline Capability Assessment for Biological Stand-Off Detection - Limited developmental capability; priority number one.
<u>Wide Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</u> Develop a 3-Hz, 128 x 128 tunable hyperspectral imager (AIRIS). Perform sensor characterization tests. Develop off-line algorithms and signal processing techniques. This DTO supports the Joint Service Light Nuclear Biological Chemical Reconnaissance System (JSLNBCRS) and Stryker programs and addresses Baseline Capability Assessment NBC Reconnaissance - Lack of sensor integration; priority number 28.	<u>Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</u> Determine optimum spectrometer performance specifications in terms of scan speed, spatial resolution, and spectral resolution. Demonstrate an enhanced FTIR and tunable IR systems with real-time data processing on an airborne platform in a recon application using the appropriate performance parameters. This DTO supports the Joint Service Light Nuclear Biological Chemical Reconnaissance System (JSLNBCRS) and

FY 2005 Targets	FY 2006 Targets
<p><u><i>Point Detection, Integrated CB</i></u></p> <p>Continue development of first generation breadboard based on millimeter wave spectroscopy for bio detection. Initiate Raman spectroscopy for the detection/identification of biological materials. Expand effort from DTO CB50 on aerosol properties for identification of chemicals.</p>	<p>Stryker programs and addresses Baseline Capability Assessment NBC Reconnaissance - Lack of sensor integration; priority number 28.</p> <p><u><i>Point Detection, Integrated CB</i></u></p> <p>Continue first generation breadboard based on millimeter wave spectroscopy for bio detection. Continue Raman spectroscopy for the detection/identification of biological materials.</p> <p><u><i>Detection of CB Contamination on Surfaces</i></u></p> <p>Initiate the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application.</p> <p><u><i>Biological Identification</i></u></p> <p>Re-initiate and leverage efforts from Medical Science and Technology in proteomics for biomarkers for the identification of biological agents in complex biological backgrounds.</p> <p><u><i>Chemical Point Detection</i></u></p> <p>Initiate the development of a micro gas analyzer with technology from DARPA. Merge requirements from Increment 2 of Joint Chemical Agent Detector as the baseline technical parameters. Focus is on real-time (less than 5 sec) detection/identification of sub miosis sensitivity levels (parts per trillion) and the expansion of the number of detectable materials to include the high priority TICs.</p>
<p><u><i>Low-Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO CB51) - Low Level Operational Toxicology Studies</i></u></p> <p>Complete cross-validation studies based on a validated dosimetric for exposure route comparison that refine operational human health risk assessments for exposure to the nerve agents. Extend the useful range of prediction out in time for inhalation exposures to GF expected in various military response settings. Initiate VX studies that extend time-effect predictive capability.</p>	<p><u><i>Low-Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO CB51) - Low Level Operational Toxicology Studies</i></u></p> <p>Continue evaluations of inhalation toxicology.</p>
<p><u><i>Biological Agent Fate</i></u></p> <p>Continue assessments of the persistence (viability) of biological warfare agents released into operational environments.</p>	<p><u><i>Biological Agent Fate</i></u></p> <p>Continue assessments of the persistence (viability) of biological warfare agents released into operational environments.</p>
<p><u><i>Individual Protection, Clothing</i></u></p> <p>Prepare and evaluate carbon-loaded fabric with nanofiber and/or membrane backing in wide widths suitable for fabrication into prototype garments, incorporating novel closure systems. Develop and evaluate the performance of a prototype intermittent Micro Climate Cooling System (MCS) vapor compression component. Develop advanced closure concepts, develop and assess conceptual models, and fabricate prototypes of best candidates. Develop swatch test technology for assessing role of wind speed in challenge penetration of Individual Protective</p>	<p><u><i>Individual Protection, Clothing</i></u></p> <p>Optimize fabrics and demonstrate performance through full system testing. Transition NTA protection to 6.3 for field evaluation. Test a full prototype Micro Climate Cooling System (MCS) (cooling unit and cooling garment) on the Thermal Manikin, and conduct a physiological study to demonstrate the performance of the intermittent MCS. Evaluate prototype closures, downselect best candidates, fabricate protective garments using best candidates for system level testing. Demonstrate wind speed effects by characterizing wind-driven challenge penetration through IPE material</p>

FY 2005 Targets	FY 2006 Targets
Equipment (IPE). <i>Individual Protection, Masks</i> Initiate and validate bio protection factor (PF) test procedures, conduct human bio-PF study, analyze data and prepare final report. Assess performance of dual sided filter concept model, develop and evaluate integration options, conduct testing to update baseline performance for concepts, and demonstrate technology and concepts for the next generation advanced mask system. Develop final technology concepts for active and passive pressurization, conduct additional unmanned and manned protection factor evaluations of all technology concepts, and develop final technology option recommendations for future mask concept development.	(swatches) and components (closures and interfaces) as a function of air velocity <i>Individual Protection, Masks</i> Develop updated system level design goals for advanced masks, complete updated technology assessment, preliminary market survey, and updated trade-off analysis, and initiate development of prototype models. Initiate efforts to identify advance seal technologies to enhance performance and comfort of future masks.
<i>End-of-Service-Life Indicators for NBC Mask Filters (DTO CB36)</i> Assess the effects of common battlespace interferents on ESLI performance. Optimize ESLI design and complete demonstration testing on ESLI filter prototype(s). Investigate new indicators (or optimize existing indicators as required) to detect sorbent depleting battlefield contaminants. This DTO will transition to the Joint Service General Purpose Mask (JSGPM) program and addresses Baseline Capability for Respiratory and Ocular Protection - Limited TIC protection; priority number 19.	
<i>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</i> Demonstrate scaled-up electrospun self-detoxifying membranes. Optimize materials and processing conditions for reactive fibers/films/membranes. Select materials from DTO and related projects. Measure chemical/aerosol breakthrough of candidate fabrics. Measure durability of candidate fabrics from all sources. Conduct toxicology and live agent testing of manufactured fabrics. Select fabric design from agent and durability testing. Manufacture prototypes. Conduct field-testing. Collect user assessments. Select overall garment design from field-testing and report findings. This DTO supports the Joint Expeditionary Collective Protection (JECP) program which addresses Baseline Capability Assessment for Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary COLPRO - Correct quantity shortfalls; priority number 25. This DTO also supports the current Joint Service Lightweight Integrated Suit Technology program.	
<i>Collective Protection, Shelters</i> Next generation airlock concepts will continue to be explored focusing on improved airflow properties and ease of use features using computer modeling as well as test-bed purge testing of multiple configurations. Novel CB closures will be fabricated, tested and down-selected	<i>Collective Protection, Shelters</i> Laboratory samples of impermeable barrier materials will be prepared and performance testing of the samples completed. Based on lab results perform down-selection and optimization of the impermeable barrier. Mature self-decontaminating reactive barrier materials. Conduct

FY 2005 Targets	FY 2006 Targets
<p>to the best performing concept. Initiate development of new impermeable chem/bio resistant barrier material, starting with a front-end analysis and identification of conceptual configurations. Complete a study on the currently fielded equipment and procedures used in entry/exit of collective protection systems. Create a model of entry/exit process and run simulations documenting the effects of key variables. Perform simulant and agent testing on cloth swatches treated with self-decontaminating chemistries. Demonstrate performance of expedient coating formulations and determine permeability.</p>	<p>entry/exit system simulant testing, validate initial computer model and updated system design. Using potential shelters conduct small scale expedient coatings tests and optimize coating formulations.</p>
<p><u>Collective Protection, Filtration</u></p> <p>Characterize and optimize performance of advance aerosol/particulate removal processes providing enhanced protection. Minimize the deleterious effects of adsorbents possessing volatile and non-volatile reactive chemicals. Assess impact of pollutants on aerosol/particulate filters. Develop regenerative filtration advanced technology demonstrators based upon temperature wing adsorption and electrical wing adsorption approaches and integration with environmental control units. Advance the developed residual life indicator hardware and initiate chemical pulsing concepts to probe filter reactive chemistry capacity.</p>	<p><u>Collective Protection, Filtration</u></p> <p>Characterize binder materials and processes for combining multiple adsorbents that are effective in the removal of ammonia, ethylene oxide, nitrogen dioxide and formaldehyde. For filter residual life indicator identify candidate chemical tracers to be evaluated to correlate the retention time of a pulse of chemical delivered to an adsorbent bed.</p>
<p><u>Advanced Air Purification System Model (DTO CB61)</u></p> <p>Identify high priority model applications, compile user and operational requirements and initiate population of databases using data in literature, existing system performance and module models. Configure lab scale system to measure required design data. This DTO supports the Joint Expeditionary Collective Protection (JECP) program and addresses Baseline Capability Assessment for Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary COLPRO - Correct quantity shortfalls; priority number 25.</p>	<p><u>Advanced Air Purification System Model (DTO CB61)</u></p> <p>Continue identification of high priority model applications, compile user and operational requirements and initiate population of databases using data in literature, existing system performance and module models. Configure lab scale system to measure required design data. This DTO supports the Joint Expeditionary Collective Protection (JECP) program and addresses Baseline Capability Assessment for Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary COLPRO - Correct quantity shortfalls; priority number 25.</p>
<p><u>Decontamination, Sensitive Equipment</u></p> <p>Conclude studies on activated sorbent suspensions in HydroFluorEthers (HFE) solvent systems. Initiate a new effort to develop reactive impregnated solvent based wiping systems. Initiate a new effort to develop a better filtration system for HFE solvent systems as a product improvement for the Joint Service Sensitive Equipment Decontamination (JSSED) acquisition effort.</p>	<p><u>Decontamination, Sensitive Equipment</u></p> <p>Continue effort to develop reactive impregnated solvent based wiping systems. Continue development of a better filtration system for HydroFluorEthers (HFE) solvent systems as a product improvement for the Joint Service Sensitive Equipment Decontamination (JSSED) acquisition effort.</p>
<p><u>Decontamination - Oxidative Formulation (DTO CB44)</u></p> <p>Complete chamber testing over operational temperature range, finish material compatibility testing, and formulate new oxidative approaches into a dry powder and/or concentrated liquid. This DTO supports the Joint Tactical Decontamination Systems (JSTDs) and addresses Baseline Capability Assessment for Equipment Decon - Decontaminants and applicators degrade equipment; priority number 18, Equipment</p>	<p><u>Decontamination, Solution Chemistry</u></p> <p>Develop an improved decontaminant for the use on aircraft and other sensitive exteriors for transition in the Joint Service Family of Decontamination Systems (JSFDS) program. Conclude development of a chlorine dioxide based man portable decon system. Investigate alternative solution based technologies for man portable devices for immediate and operational decon scenarios.</p>

FY 2005 Targets	FY 2006 Targets
Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, and Fixed Site Decontamination – Applicators degrade equipment, facilities, and material; priority number 34.	
<i><u>Threat Agents and Simulants</u></i> Continue and expand efforts to determine and validate new synthesis targets. Continue to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CWA simulants. Continue to catalog agent properties in searchable data base. Continue investigations of inhalation toxicity of NTAs.	<i><u>Threat Agents</u></i> Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Complete characterization of the fundamental properties of Y. pestis and initiate work on B. mallei. Initiate new efforts to identify CB simulants and catalog data.
<i><u>Bio-Threat Agents</u></i> Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of Y. pestis and initiate work on B. mallei. Complete characterization of fundamental properties of a viral family and continue characterization of a second viral family selected by biodefense priorities. Complete improvement of Erwinia herbicola antigenicity, and continue exploration of novel "peptide-based" bio simulants and research on a new viral simulant. Continue upgrading the data in the agent/simulant knowledge base technical information system and initiate the collection and quality assessment of toxicology data. Investigate physical properties and decontamination properties of B. mallei and baculovirus	
<i><u>Aerosol Technology</u></i> Continue investigations of approaches to advanced inlets for aerosol collection in high air speed conditions. Continue experimental studies of novel collectors, electrostatic collector, impeller, mini-slit, and other low power aerosol collection devices. Continue characterization of emerging collectors and collection technology. Upgrade existing chambers and wind tunnels. Continue evaluations of new and prototype chemical detectors using chemical stimulant aerosols. Continue CFD modeling for the windbreak approach of sampling omnidirectionally from high speed flows.	<i><u>Aerosol Technology</u></i> Continue investigations of approaches to advanced inlets for aerosol collection in high air speed conditions. Continue experimental studies of novel collectors.
<i><u>Environmental Fate of Agents (DTO CB42) - Predictive Modeling</u></i> Evaluate Agent Fate secondary evaporation model versus the VLSTRACK module and evaluate each with agent lab trials to determine accuracy of downwind vapor predictions. Tune model/module and integrate into Joint Effects Model (JEM). Complete agent/inert substrate prediction model from lab-scaled wind tunnel data. Continue to work the scaling of agent vapor concentrations from laboratory to outdoor test conditions. Continue CHEMRAT update with new agent fate test data. Continue to update secondary	<i><u>Environmental Fate of Agents (DTO CB42) - Predictive Modeling</u></i> Complete secondary evaporation models and conduct predictions of field trials. Transition updates into JEM and JOEF. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis - Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to

FY 2005 Targets	FY 2006 Targets
evaporation model with new agent fate test data and incorporate into JEM. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis – Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.	decontaminate large areas / interiors of facilities; priority number 39.
<u><i>Environmental Fate of Agents (DTO CB42) - Methodology Development</i></u> Determine degradation products of agents on surfaces of interest such as concrete. Examine the fate of VX, GD and NTA on asphalt by NMR. Examine the fate of V analogs, NTAs and thickened agents on surfaces under different temperature and humidity conditions by HS-SPME. Determine sorption and fate of VX on sand and clay soil. Determine sorption and fate of GD and VX on assembled test soil. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis - Lack of Analysis Tools; priority number six, Equipment Decontamination – Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.	<u><i>Environmental Fate of Agents (DTO CB42) - Methodology Development</i></u> Complete studies to determine degradation products of agents on surfaces of interest such as concrete, asphalt, grass, and soil. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis – Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.
<u><i>Environmental Fate of Agents (DTO CB42) - Lab/Large-Scale Wind Tunnel Studies</i></u> Continue surface residual agent testing to determine contamination levels. Complete surface evaporation tests of VX, GD, and HD on a non-porous substrate. Start surface evaporation testing of thickened CWA's on soil, asphalt and concrete. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis - Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.	<u><i>Environmental Fate of Agents (DTO CB42) - Lab/Large-Scale Wind Tunnel Studies</i></u> Complete measurements of large scale and outdoor test data for original test matrix. Complete validation tests of surface evaporation model for agents on surfaces. Complete and document surface residual agent testing. Complete surface evaporation tests of VX, GD and HD on concrete, asphalt, grass, and soil. Complete measurement of surface evaporation of thickened HD, GD and VX on asphalt and concrete. This DTO addresses Baseline Capability Assessment for Battle Space Analysis - Lack of Hazard assessment tools; priority number five, Battle Space Analysis - Lack of Analysis Tools; priority number six, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, NBC Reconnaissance - Lack of sensor integration; priority number 28, and Fixed Site Decon - Inability to decontaminate large areas / interiors of facilities; priority number 39.
<u><i>Supporting Science and Technology</i></u> Modeling and Simulation - Complete and transition agent/inert substrate prediction module to JOEF and JEM.	
<u><i>Chemical and Biological Hazard Environment</i></u>	<u><i>Chemical and Biological Hazard Environment</i></u>

FY 2005 Targets	FY 2006 Targets
<u><i>Prediction (DTO CB55) and Hazard Prediction with Nowcasting (DTO CB62)</i></u> Continue refinement of MESO code for transition to Joint Effects Model (JEM). Perform independent validation and verification of a computation fluid dynamics - based tools set developed by Naval Research Lab. The DTOs support Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of analysis tools; priority number six.	<u><i>Prediction (DTO CB55) and Hazard Prediction with Nowcasting (DTO CB62)</i></u> Complete DTO CB55. Continue DTO CB62 to enhance near-surface environmental characterization and demonstrate improvements using the Joint Effects Model (JEM). Supports Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of analysis tools; priority number six.
<u><i>CBDP Decision Capability (formerly Simulation Based Acquisition)</i></u> Complete tool design and begin prototype construction and testing. Consolidate analytic library and analysis methodology for use by program for rapid decision making. Use iterative user-focused design techniques to enhance tool/capability usability and acceptance.	<u><i>CBDP Decision Capability</i></u> Continue building the analytical framework. Identify gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development.
<u><i>Battlespace Management</i></u> Continue efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses within the current and planned C4ISR architecture. Begin applied research into integrating existing Joint Program Manager Information Systems (JPM-IS) application into the Global Information Grid (GIG) and Net-Centric Enterprise System (NCES).	<u><i>Battlespace Management</i></u> Build Net-Centric Enterprise Systems (NCES) modules for migration to test environment. Continue sensor-data fusion and source term location technologies.
<u><i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i></u> Test and finalize toward Joint Operational Effects Federation (JOEF) transition. Develop mobile forces module. Conduct internal Verification and Validation (V&V). Prepare for external V&V by PM. This DTO supports Baseline Capability Assessment for Battle Space Management – Lack of automated decision tools; priority number eight and Battle Space Management - Lack of interface with the COP; priority number nine.	<u><i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i></u> Develop mobile forces modules. Identify new applications for Joint Operational Effects Federation (JOEF). Begin assessing integration with theater-level models. This DTO supports Baseline Capability Assessment for Battle Space Management - Lack of automated decision tools; priority number eight and Battle Space Management - Lack of interface with the COP; priority number nine.

3.5.1.6 Assessment of Chemical and Biological Defense Applied Research. Applied research efforts in FY04 for project CB2 were at least minimally effective. Many areas of CB defense applied research were successful. The assessment is based on two factors: (1) several DTOs in this area were rated yellow by the TARA and one was rated red. All efforts have developed plans to address concerns identified and will be re-assessed. (2) Several technologies successfully transitioned to advanced development. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated. Additionally, execution continued on several Congressionally added projects, including the CB Defense Initiatives Fund.

3.5.2 Medical Biological Defense Applied Research (Project TB2)

This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnological approaches and

advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTO); science and technology programs in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines); and directed research efforts, including the Chemical and Biological Defense Initiative (CBDI) fund.

3.5.2.1 TB2 Performance Goal (Outcome). The goal of CB defense medical biological defense applied research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of BW agents in order to develop preventive and therapeutic protection and diagnostic technologies for BW agents.

3.5.2.2 TB2 Outcome Measure

TB2 is minimally effective when	TB2 is successful when
<ul style="list-style-type: none"> The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> Bacterial Therapeutics, Toxin Vaccines, Bacterial Vaccines, Toxin Therapeutics, Viral Therapeutics, Viral Vaccines, Diagnostic Technologies, and Protocols to Enhance Biological Defense. The results of research are published in peer-reviewed journals or presented at scientific conferences Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development All DTOs are rated GREEN by the TARA Panel.

3.5.2.3 Metric Description. The metric for TB2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.5.2.4 TB2 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u><i>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</i></u> Initiate development of animal models of aerosol infection with filoviruses. Initiate applied research to define correlates of immunity that protect against disease from filoviruses. Develop animal models for Ebola-Sudan virus. Conduct preliminary characterization of leading vaccine candidates.	<u><i>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</i></u> Initiated development of animal models of aerosol infection with filoviruses. Initiated applied research to define correlates of immunity that protect against disease from filoviruses. Developed animal models for Ebola-Sudan virus. Conducted preliminary characterization of leading vaccine candidates.
<u><i>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</i></u> Continue preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for cidofovir and provide technical data and support to the drug license holder. Compare the variola animal model to the monkeypox animal model and human monkeypox to qualify models to be proposed under the FDA animal efficacy rule. Initiate	<u><i>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</i></u> Continued preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for cidofovir and provide technical data and support to the drug license holder. Compared the variola animal model to the monkeypox animal model and human monkeypox to qualify models to be proposed under the FDA animal efficacy rule. Initiated

FY2004 Targets	Actual Performance
development of an oral prodrug of cidofovir.	development of an oral prodrug of cidofovir.
<u>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</u> Develop laboratory-based test and evaluation standards for comparing similar diagnostic/detection assays and reagents. Elevate assays, previously handed off to advanced development, to consistent test and evaluation standards and prepare technical data packages for these assays/reagents.	<u>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</u> Developed laboratory-based test and evaluation standards for comparing similar diagnostic/detection assays and reagents. Elevated assays, previously handed off to advanced development, to consistent test and evaluation standards and prepared technical data packages for these assays/reagents.
<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</u> Initiate applied research to define correlates of immunity that protect against disease from alphaviruses (EEE and WEE viruses). Develop DNA and replicon-based vaccine constructs/platforms as western and eastern equine encephalitis (WEE/EEE) vaccine candidates.	<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</u> Initiated applied research to define correlates of immunity that protect against disease from alphaviruses (EEE and WEE viruses). Developed DNA and replicon-based vaccine constructs/platforms as western and eastern equine encephalitis (WEE/EEE) vaccine candidates.
<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Investigate recombinant human antibodies as passive immunotherapeutics. Synthesize structural analogs of active-site inhibitors identified by high-throughput screening. Identify candidate botulinum neurotoxin (BoNT) receptor antagonists as therapeutic candidates. Establish a central database and compound repository.	<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Investigated recombinant human antibodies as passive immunotherapeutics. Synthesized structural analogs of active-site inhibitors identified by high-throughput screening. Identified candidate botulinum neurotoxin (BoNT) receptor antagonists as therapeutic candidates. Established a central database and compound repository.
<u>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</u> Develop assays methodologies and drug formulations or prodrugs for analysis. Evaluate monoclonal antibodies to viral specific proteins for their ability to neutralize virus. Identify critical host-cell proteins integral to viral replication, viral budding, or viral entry. Generate Ebola virus VP40 and GP mutant constructs as well as a tetra cysteine-fusion of VP40 in mammalian and bacterial expression vectors.	<u>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</u> Developed assays methodologies and drug formulations or prodrugs for analysis. Evaluated monoclonal antibodies to viral specific proteins for their ability to neutralize virus. Identified critical host-cell proteins integral to viral replication, viral budding, or viral entry. Generated Ebola virus VP40 and GP mutant constructs as well as a tetra cysteine-fusion of VP40 in mammalian and bacterial expression vectors.
<u>Therapeutics, Bacterial</u> Perform additional in vivo studies on efficacy of selected antimicrobial compounds against various bacterial threat agents in small animal models. Initiate studies of selected Food and Drug Administration (FDA)-licensed antibiotics to support consideration for changing label indications against biological warfare (BW) threat agents.	<u>Therapeutics, Bacterial</u> Performed additional in vivo studies on efficacy of selected antimicrobial compounds against various bacterial threat agents in small animal models. Initiated studies of selected Food and Drug Administration (FDA)-licensed antibiotics to support consideration for changing label indications against biological warfare (BW) threatagents.
<u>Therapeutics, Toxin</u> Initiate testing of lead inhibitors of SE using in vivo model systems for assessment of therapeutic efficacy. Standardize in vivo model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy.	<u>Therapeutics, Toxin</u> Initiated testing of lead inhibitors of SE using in vivo model systems for assessment of therapeutic efficacy. Standardized in vivo model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy.
<u>Therapeutics, Viral</u> Develop fluorescent-based methods for high-throughput	<u>Therapeutics, Viral</u> Developed fluorescent-based methods for high-

FY2004 Targets	Actual Performance
screening for antiviral efficacy and cellular toxicity. Continue research to identify pharmacological compounds provided by industry that may intervene in filovirus-induced shock. Continue the assessment of the therapeutic action of compounds in mouse models of filovirus infection. Complete research for development of a variola animal model at CDC.	throughput screening for antiviral efficacy and cellular toxicity. Continued research to identify pharmacological compounds provided by industry that may intervene in filovirus-induced shock. Continued the assessment of the therapeutic action of compounds in mouse models of filovirus infection. Completed research for development of a variola animal model at CDC.
<u><i>Therapeutics, Heteropolymer Monoclonal Antibody-Based Technology</i></u> Produce and purify milligram quantities of H25 antibody for a 4-liter scale spinner production. Determine functional and biophysical properties of the purified antibody. Confirm the utility and acceptability of the antibody produced from the cell lines for further product development. Develop analytical transfer methods and assays for monoclonal antibodies (MAbs) and heteropolymers (HPs) and conduct animal studies.	<u><i>Therapeutics, Heteropolymer Monoclonal Antibody-Based Technology</i></u> Produced and purified milligram quantities of H25 antibody for a 4-liter scale spinner production. Determined functional and biophysical properties of the purified antibody. Confirmed the utility and acceptability of the antibody produced from the cell lines for further product development. Developed analytical transfer methods and assays for monoclonal antibodies (MAbs) and heteropolymers (HPs) and conduct animal studies.
<u><i>Therapeutics, Bacterial, Heteropolymer Technologies for Anthrax Immunity</i></u> Evaluate protective efficacy in rabbits exposed to lethal doses of aerosolized anthrax using the proprietary anthrax antibody, ETI-204. Assess the level of bacteremia in treated versus untreated animals.	<u><i>Therapeutics, Bacterial, Heteropolymer Technologies for Anthrax Immunity</i></u> Evaluated protective efficacy in rabbits exposed to lethal doses of aerosolized anthrax using the proprietary anthrax antibody, ETI-204. Assessed the level of bacteremia in treated versus untreated animals.
<u><i>Therapeutics, Bacterial, Rapid Antibody-Based Biological Countermeasures</i></u> Develop diagnostic and therapeutic antibodies against anthrax and identify new targets associated with anthrax and plague pathology. Identify additional targets associated with anthrax and plague virulence and screen for novel antibodies to detect and protect against related bioweapons. Discover novel, validated protein targets. Develop diagnostic antibodies optimized for affinity and selectivity to biowarfare agents. Create a collection of human therapeutic antibodies for passive immunity protection against bioweapons and more effective treatment against pathogens and toxins.	<u><i>Therapeutics, Bacterial, Rapid Antibody-Based Biological Countermeasures</i></u> Developed diagnostic and therapeutic antibodies against anthrax and identified new targets associated with anthrax and plague pathology. Identified additional targets associated with anthrax and plague virulence and screen for novel antibodies to detect and protect against related bioweapons. Discovered novel, validated protein targets. Developed diagnostic antibodies optimized for affinity and selectivity to biowarfare agents. Created a collection of human therapeutic antibodies for passive immunity protection against bioweapons and more effective treatment against pathogens and toxins.
<u><i>Diagnostic Technologies</i></u> Continue to apply new diagnostic approaches directed toward early recognition of infection, selecting technologies that can be adapted to current and future comprehensive integrated diagnostic systems. Continue laboratory and field studies using relevant clinical samples to apply new technological approaches for diagnosis of potential biological warfare threat agents. Continue to apply new technological approaches for concentrating and processing clinical samples to support rapid agent identification and to apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.	<u><i>Diagnostic Technologies</i></u> Continued to apply new diagnostic approaches directed toward early recognition of infection, selecting technologies that can be adapted to current and future comprehensive integrated diagnostic systems. Continued laboratory and field studies using relevant clinical samples to apply new technological approaches for diagnosis of potential biological warfare threat agents. Continued to apply new technological approaches for concentrating and processing clinical samples to support rapid agent identification and to apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.
<u><i>Vaccines, Bacterial</i></u> Complete the evaluation of potential subunit and live-attenuated glanders vaccine candidates in small animal models and prepare a technical data package	<u><i>Vaccines, Bacterial</i></u> Completed the evaluation of potential subunit and live-attenuated glanders vaccine candidates in small animal models and prepared a technical data package

FY2004 Targets	Actual Performance
summarizing the glanders vaccine research program. Perform preliminary studies toward development of an acellular brucella vaccine candidate. Continue to perform in vitro and in vivo studies to support advanced development of the rPA vaccine candidate.	summarizing the glanders vaccine research program. Performed preliminary studies toward development of an acellular brucella vaccine candidate. Continued to perform in vitro and in vivo studies to support advanced development of the rPA vaccine candidate.
<u>Vaccines, Toxin</u> Initiate studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Initiate studies to increase immunogenicity of recombinant BoNT heavy chain (Hc) subunit vaccine candidates by varying adjuvant and/or method of delivery. Continue developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Qualify in vivo and in vitro concept model systems for assessment of recombinant ricin vaccine candidate efficacy and surrogate endpoints of human clinical efficacy.	<u>Vaccines, Toxin</u> Initiated studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Initiated studies to increase immunogenicity of recombinant BoNT heavy chain (Hc) subunit vaccine candidates by varying adjuvant and/or method of delivery. Continued developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Qualified in vivo and in vitro concept model systems for assessment of recombinant ricin vaccine candidate efficacy and surrogate endpoints of human clinical efficacy.
<u>Vaccines, Viral</u> Investigate the use of the oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates to determine their effect on immunity conferred by the vaccines.	<u>Vaccines, Viral</u> Investigated the use of the oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates to determine their effect on immunity conferred by the vaccines.
<u>Vaccines, Needle-less Delivery Methods for Vaccines</u> Examine the potential for intradermal (ID) delivery to provide antigen dose-sparing benefits, faster seroconversion, and reduction or elimination of alum. Examine the safety and immunogenicity of the ID delivery of the anthrax rPA with or without alum adjuvant. Compare intramuscular (IM) injection with standard needles. Pursue further development of formulation technologies for rPA and rSEB providing improved shelf-life stability. Develop and test rapidly reconstituting rPA powders and systems for ID delivery in mouse challenge studies. Identify rapidly reconstituting formulations and delivery systems for the rSEB vaccine candidate.	<u>Vaccines, Needle-less Delivery Methods for Vaccines</u> Examined the potential for intradermal (ID) delivery to provide antigen dose-sparing benefits, faster seroconversion, and reduction or elimination of alum. Examined the safety and immunogenicity of the ID delivery of the anthrax rPA with or without alum adjuvant. Compared intramuscular (IM) injection with standard needles. Pursued further development of formulation technologies for rPA and rSEB providing improved shelf-life stability. Developed and test rapidly reconstituting rPA powders and systems for ID delivery in mouse challenge studies. Identified rapidly reconstituting formulations and delivery systems for the rSEB vaccine candidate.
<u>Vaccines, Viral, Multivalent Ebola, Marburg Filovirus Program</u> Develop a multivalent vaccine platform capable of inducing potent humoral and cellular immune responses against two strains of Ebola viruses (bivalent) and three strains of Marburg viruses (trivalent) for biodefense.	<u>Vaccines, Viral, Multivalent Ebola, Marburg Filovirus Program</u> Developed a multivalent vaccine platform capable of inducing potent humoral and cellular immune responses against two strains of Ebola viruses (bivalent) and three strains of Marburg viruses (trivalent) for biodefense.
<u>Vaccines, Bacterial, Oral Anthrax and Plague Vaccine</u> Develop an oral combination vaccine against anthrax and plague using proprietary technology for attenuated live bacterial vaccines. Support preclinical animal testing of vaccine constructs developed for the oral combination vaccine against anthrax and plague.	<u>Vaccines, Bacterial, Oral Anthrax and Plague Vaccine</u> Developed an oral combination vaccine against anthrax and plague using proprietary technology for attenuated live bacterial vaccines. Supported preclinical animal testing of vaccine constructs developed for the oral combination vaccine against anthrax and plague.
<u>Vaccines, Bacterial, Novel Pharmaceuticals for Anthrax</u> Develop the Helinz-treated vaccine platform, with application in both cancer and infectious disease, including those agents that pose bioterrorism threats.	<u>Vaccines, Bacterial, Novel Pharmaceuticals for Anthrax</u> Developed the Helinz-treated vaccine platform, with application in both cancer and infectious disease, including those agents that pose threats to bioterrorism.
<u>Medical Biological Warfare Defense, Global Pathogen</u>	

FY2004 Targets	Actual Performance
<u>Portal</u> Collect and collate genetic information about pathogens from the CDC and the National Institute of Allergy and Infectious Diseases "A", "B", and "C" lists of pathogens and their close relatives using a global pathogen portal bioinformatic software architecture.	
<u>Medical Biological Warfare Defense, Vaccines and Therapeutics to Counter Biothreats</u> Conduct applied research to develop vaccines and therapeutics to counter BW threat agents	<u>Medical Biological Warfare Defense, Vaccines and Therapeutics to Counter Biothreats</u> Conducted applied research to develop vaccines and therapeutics to counter BW threat agents.
<u>Medical Biological Warfare Defense, Advanced Emergency Medical Response</u> Conduct applied research toward development of advanced emergency medical response capabilities.	<u>Medical Biological Warfare Defense, Advanced Emergency Medical Response</u> Conducted applied research toward development of advanced emergency medical response capabilities.
	<u>Medical Biological Warfare Defense, Advanced</u> Conducted research on the treatment of late stage biological weapon and battle wound related sepsis by removal of extracorporeal mediators.

3.5.2.5 TB2 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>Therapeutics, Bacterial</u> Perform therapeutic efficacy studies in non-human primate models. Continue studies on selected FDA-licensed antimicrobial compounds to support consideration for changing label indications for use against BW threat agents.	<u>Therapeutics, Bacterial</u> Test Antibacterial cytokine-based therapeutic candidates. Test CpG motifs (stimulators of immune response) in conjunction with antibiotics for plaque therapy in an animal model. Continue to advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Enhance aerobiology capabilities and animal model development to facilitate bacterial therapeutics research.
<u>Therapeutics, Toxin</u> Develop surrogate endpoints of human clinical efficacy for SE therapeutics.	<u>Therapeutics, Toxin</u> Develop formulations or prodrugs to overcome problems with metabolism, bioavailability or pharmacokinetics of compounds with otherwise acceptable antiviral profiles of new compounds. Test efficacy of combinations of monoclonal antibodies against multiple toxin serotypes in cell-based systems. Continue ongoing proof-of-concept studies with lead toxin therapeutics <i>in vivo</i> using qualified surrogate endpoints of human clinical efficacy.
<u>Therapeutics, Viral</u> Assess therapeutic action of pharmacological compounds provided by industry in mouse and non-human primate models of filovirus infection.	<u>Therapeutics, Viral</u> Standardize leading antivirals in appropriate animal models. With lead compounds, put into place strategic plan for licensure and manufacturing.
<u>Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Conduct studies to evaluate drug efficacy of IV cidofovir in primate models that support the FDA Animal Efficacy Rule. Evaluate activity in monkeypox primate animal model. Continue evaluation of oral prodrug of cidofovir to determine if it is a replacement for IV cidofovir. Complete development of simple high throughput <i>in vitro</i> drug screening assay. Identify new molecular	<u>Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Conduct initial evaluation in pock lesion variola primate model at the Centers for Disease Control and Prevention. Evaluate oral cidofovir prodrug against monkeypox in primate model. Conduct initial studies to determine drug efficacy. Evaluate minimal and sufficient viral therapeutic requirements such as dose, route, and area under the curve. Perform

FY 2005 Targets	FY 2006 Targets
targets and develop assays specific for those targets. Evaluate antiviral activity of collections of compounds to identify lead structures for development into antiviral drugs with emphasis on compounds acting through a different mechanism than inhibition of viral DNA polymerase. Identify and test leading antivirals in appropriate animal models. Identify potential mediators of shock or toxemia and determine the basis for the pathogenesis of shock or toxemia in animal models.	appropriate testing in nonhuman primates for FDA licensure consideration under the FDA Animal Efficacy Rule.
<u><i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i></u> Investigate recombinant human antibodies as passive immunotherapeutics. Synthesize structural analogs of active-site inhibitors identified by high-throughput screening. Identify candidate BoNT receptor antagonists as therapeutic candidates. Establish a central database and compound repository. Initiate ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum intoxication.	<u><i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i></u> Develop lead mixtures of human antibodies against BoNT as passive immunotherapeutics in vivo. Complete in vitro testing of combinations of monoclonal antibodies against multiple Botulinum Neurotoxin (BoNT) serotypes and proof-of-concept studies with lead BoNT active-site inhibitors and/or receptor antagonists in vivo using qualified surrogate endpoints of human clinical efficacy. Information generated by this research will be used to develop a strategy, in concert with the advanced developer, for development of BoNT therapeutic candidates. Information generated by this research will be used to develop a technology development plan for non-clinical studies of optimum therapeutic candidates/treatment modalities.
<u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Generate mutant Marburg virus proteins and evaluate their ability to interact with other Marburg virus proteins. Develop information on characteristics distinguishing protective and nonprotective monoclonal antibodies.	<u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Identify the structural requirements of the filoviral proteins that are essential for their function. Identify structure/function relationships that are essential for the virion formation and host cell interactions. Determine previously unsolved 3D structures of filoviral proteins and filoviral proteins in complex with host cell proteins. Refine (energetic and hydrodynamic) crystallographic coordinates, and/or generate sequence based homology models of identified targets. Apply bioinformatics, chemoinformatics and molecular modeling tools to further optimize lead therapeutic compounds.
<u><i>Diagnostic Technologies</i></u> Focus on multiplexing nucleic acid and immunoassays for the detection of identified threat agents in clinical samples. Invest in improving and multiplexing existing assays, as new genomic data and techniques become available. Investigate recombinant DNA technologies for immunodiagnostic reagent production. Pursue toxin diagnostics. Coordinate pursuit of diagnostic approaches to the early recognition of infections and the evaluation of systems compatible with future comprehensive integrated diagnostics. Test developed assays, reagents and sample preparation techniques and platforms in field studies. Investigate the use of proteomics to develop immunologic assays for pathogen detection. Investigate novel pathogen detection systems.	<u><i>Diagnostic Technologies</i></u> Continue to develop/multiplex nucleic acid and immunoassays for the detection of identified threat agents in clinical samples. Invest in improving and multiplexing existing assays, as new genomic data and techniques become available. Pursue using recombinant DNA technologies for immunodiagnostic reagent production. Develop gene sets correlating host immune response with exposure to endemic pathogens/threat agents. Test on existing molecular diagnostic platforms. Evaluate systems compatible with future comprehensive integrated diagnostics. Continue to test developed assays, reagents and sample preparation techniques and platforms in field studies. Complete evaluation of new chemistries for identifying biological warfare agents.

FY 2005 Targets	FY 2006 Targets
Analyze clinical samples obtained from human vaccines receiving biodefense vaccines to evaluate host responses to the immunizations.	Apply proteomics finding to the development of immunologic assays for pathogen detection.
<u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u> Continue to elevate previously transitioned assays to test and evaluation standards established during FY04.	<u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u> Continue to elevate previously transitioned assays to test and evaluation standards established during FY04.
<u><i>Vaccine Research Support</i></u> Continue to develop lead vaccine candidates against plague (F1-V fusion antigen vaccine) and anthrax (rPA vaccine). Evaluate the role of capsule in the development of a generation-after-next anthrax vaccine. Investigate anthrax spore interactions with host cells and characterization of diverse <i>B. anthracis</i> strains for vaccine resistance. Continue studies on the ability of functional domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Accelerate studies to increase immunogenicity of existing recombinant BoNT heavy chains (Hc) subunit vaccine candidates via adjuvants and/or method of delivery. Develop in process and release assays for recombinant BoNT Hc vaccine candidates. Test recombinant ricin vaccine (rRTA) candidate stability. Develop surrogate endpoints of clinical efficacy for higher animal species in ricin vaccine adjuvant studies. Test novel adjuvants with lead ricin vaccine candidate. Determine stability of SE vaccine candidates (in cGMP lots). Test oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates. Complete studies on correlates of immunity that protect against disease from filoviruses and alphaviruses. Evaluate the use of Virus-Like Particles (VLP) as antigen for vaccines for filoviruses. Begin evaluation of a VEE replicon-based Marburg virus vaccine candidate.	<u><i>Vaccine Research Support</i></u> Initiate the evaluation of intracellular pathogen candidate antigens using animal model systems including the use of alternative delivery platforms. Continue support studies for F1-V and rPA candidate vaccines in phase 1 studies. Begin immunogenicity studies for <i>Bacillus</i> generic vaccine target antigens. Evaluate B and T cell epitope mapping of lead protective antigen candidates. Continue to evaluate novel antigen targets for anthrax and plague vaccine development. Examine in vivo antigen expression/recognition in NHP. Evaluate the immunogenicity of intact catalytic and translocation domains of botulinum neurotoxins (BoNT). Continue developing in process and release assays for recombinant BoNT Hc vaccine candidates. Continue recombinant ricin vaccine candidate stability testing. Continue to develop surrogate endpoints of clinical efficacy for higher animal species in ricin vaccine adjuvant studies. Clone and express proposed SEA/SEB structural determinants; determine stability, raise neutralizing antibodies and test for cross-reactivity among SE serotypes using in vitro systems. Analyze WEE/EEE mutants with various engineered attenuating mutations. Evaluate target antigens for Ebola virus vaccine development. Explore additional use of Virus-Like Particles (VLP) as antigen for vaccines for filoviruses. Continue the evaluation of a VEE replicon-based Marburg virus vaccine candidate.
<u><i>Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</i></u> Continue to analyze mutants with various engineered attenuating mutations to determine their suitability for use as vaccine platforms. Enhance studies to establish an eastern equine encephalitis (EEE) virus non-human primate efficacy model.	<u><i>Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</i></u> Evaluate new EEE vaccine approaches in animal models in combination with WEE vaccine construct(s) and already transitioned VEE vaccine candidate V3526 or alternate VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms.
<u><i>Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</i></u> Incorporate antigen targets from earlier studies to improve vaccine candidates as determined from characterization studies and concurrent testing.	
	<u><i>Genetically Engineered Threats</i></u> Complete determination of spore germination inhibitors and their effectiveness.
	<u><i>Rapid Detection, Threat Assessment and Attribution of</i></u>

FY 2005 Targets	FY 2006 Targets
	<p><u><i>Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64)</i></u></p> <p>This new DTO will provide for rapid, inexpensive, high-throughput, microarray-based DNA resequencing of biothreat agent genomes, whether they are naturally occurring, newly arising, or genetic engineered strains. The goal is to develop the capability to perform whole-genome sequencing in single laboratories with minimal space and personnel requirements at less than 1% of the current cost of existing, non-DoD industrial genome sequencing centers. Rapid, inexpensive genomic resequencing of biothreat agent genomes enables immediate definitive identification of the organism and provides specific data on the presence of any engineered elements. Develop collection procedures and expand biothreat agent strain collection, focusing on <i>Bacillus anthracis</i> and <i>Yersinia pestis</i>. Sequence 6 <i>B. anthracis</i> group genomes; release data to other relevant DoD projects. Demonstrate, evaluate two high-density microarray systems, Affymetrix, Inc. and Nimblegen Systems, as whole-genome resequencing platforms. Develop, implement data analysis pipeline.</p>
	<p><u><i>Multiagent Vaccines, Multi-agent (molecular) Vaccines for Bio-Warfare Agents (DTO CB65)</i></u></p> <p>This is a new DTO that will focus on the development of a trivalent vaccine based on a prototype anthrax/plague DNA vaccine platform. Develop the optimal backbone anthrax/plague vaccine platform. Focus on DNA vector delivery systems which stimulate protective immunity following minimal dosing. Identify the third component of the bio-threat agent vaccine target/targets and their subsequent expression from the vaccine platform.</p>
	<p><u><i>Radioprotectants</i></u></p> <p>Identify and test, from a prioritized list of approximately 20 agents, two candidates for efficacy in a rodent model; the degree of protection at a radiation dose that normally causes approximately 90% lethality within 30 days (LD 90/30).</p>

3.5.2.6 Assessment of Medical Biological Defense Applied Research. Applied research efforts in FY04 for project TB2 were effective. Many areas of medical biological defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY04.

3.5.3 Medical Chemical Defense Applied Research (Project TC2)

This project funds medical chemical defense applied research and emphasizes the prevention of chemical casualties through application of pharmaceuticals for prevention and treatment of the toxic effects of nerve, blister, respiratory, and blood agents. This project supports applied

research of prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic drug compounds that have the potential to counteract the lethal, physical, and behavioral toxicities of chemical agents. It also supports development of medical chemical defense materiel that ensures adequate patient care, field resuscitation, and patient management procedures. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Nerve Agent Defense, Vesicant Agent Defense and Chemical Warfare Agent (CWA) Defense), and directed research efforts (Low Level CWA Exposure, Non- Traditional Agents (NTAs), and Mustard Gas Antidote).

3.5.3.1 TC2 Performance Goal (Outcome). The goal of medical chemical defense applied research is to increase scientific understanding of the mechanisms of action and effects of CW agents in order to demonstrate and develop technologies for preventive and therapeutic protection and diagnostics.

3.5.3.2 TC2 Outcome Measure

TC2 is minimally effective when	TC2 is successful when
<ul style="list-style-type: none"> The results provide fundamental information in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> diagnostics, low-level toxicology, pre-treatments, therapeutics, novel threats, optical recognition technologies, new detection technologies. The results of research are published in peer-reviewed journals or presented at scientific conferences Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development All DTOs are rated GREEN by the TARA Panel.

3.5.3.3 Metric Description. The metric for TC2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.5.3.4 TC2 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Continue assay development, stability studies, and studies to identify and characterize a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.	<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Continue assay development, stability studies, and studies to identify and characterize a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.
<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assess short-term behavioral, physiological, and neuropathological effects of VX nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness. Initiate studies on the effects of current prophylactic and therapeutic treatments on the maximum tolerated dose for repeated CWA exposures and on other indices of chemical agent toxicity.	<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assess short-term behavioral, physiological, and neuropathological effects of VX nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness. Initiate studies on the effects of current prophylactic and therapeutic treatments on the maximum tolerated dose for repeated CWA exposures and on other indices of chemical agent toxicity.
<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u>	<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u>

FY2004 Targets	Actual Performance
Determine the effects of NTAs on energy metabolism of cardiac cells and the effectiveness of decontamination on percutaneous NTAs. Conduct electrophysiological evaluation of cardiovascular, respiratory, muscular and cortical dysfunction.	Determine the effects of NTAs on energy metabolism of cardiac cells and the effectiveness of decontamination on percutaneous NTAs. Conduct electrophysiological evaluation of cardiovascular, respiratory, muscular and cortical dysfunction.
<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Determine efficacy of midazolam and anticholinergic drug combinations against seizures and lethality caused by nerve agents. Determine minimal amount of atropine needed to sustain survival in non-human primates exposed to nerve agent.	<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Determine efficacy of midazolam and anticholinergic drug combinations against seizures and lethality caused by nerve agents. Determine minimal amount of atropine needed to sustain survival in non-human primates exposed to nerve agent.
<u>Nerve Agent Defense, Biological Scavenger</u> Determine pharmacokinetics of CWAs and the impact of pretreatment in guinea pigs. Determine x-ray crystallographic structure of catalytic scavengers. Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Characterize animal models to test efficacy of nerve agent bioscavengers. Test physiologic pharmacokinetic model of CWAs.	<u>Nerve Agent Defense, Biological Scavenger</u> Determine pharmacokinetics of CWAs and the impact of pretreatment in guinea pigs. Determine x-ray crystallographic structure of catalytic scavengers. Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Characterize animal models to test efficacy of nerve agent bioscavengers. Test physiologic pharmacokinetic model of CWAs.
<u>Nerve Agent Defense, Neuroprotection</u> Test Food and Drug Administration (FDA)-approved drugs shown to be neuroprotective in both anatomic and behavioral studies.	<u>Nerve Agent Defense, Neuroprotection</u> Test Food and Drug Administration (FDA)-approved drugs shown to be neuroprotective in both anatomic and behavioral studies.
<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Conduct screening of candidate antivesicant compounds. Develop in vitro and in vivo models to support efficacy studies of new antivesicant countermeasures.	<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Conduct screening of candidate antivesicant compounds. Develop in vitro and in vivo models to support efficacy studies of new antivesicant countermeasures.
<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Identify candidate treatment strategies and collate findings in concert with medical experts and relevant research teams. Define in vitro/in vivo models, establish pathophysiological endpoints, and define cellular and tissue consequences of exposure.	<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Identify candidate treatment strategies and collate findings in concert with medical experts and relevant research teams. Define in vitro/in vivo models, establish pathophysiological endpoints, and define cellular and tissue consequences of exposure.
<u>Vesicant Agent Defense, Mustard Gas Antidote</u> Enhance the effectiveness of Signal Transduction Inhibition Methodology Antioxidant Liposomes (STIMAL), also known as the Redox Regulating Liposome (RRL), by further product development. Elucidate the pathophysiology of mustard agents in previously developed in vitro and in vivo models. Explore additional modalities such as pharmacogenomically-based drugs and complement blockade. Complete initial efficacy studies of STIMAL against HD. Conduct detailed studies on the inhalation of mustards (bis-2-CEES) to determine if oxidative stress is a significant part of the pathophysiology.	<u>Vesicant Agent Defense, Mustard Gas Antidote</u> Enhance the effectiveness of Signal Transduction Inhibition Methodology Antioxidant Liposomes (STIMAL), also known as the Redox Regulating Liposome (RRL), by further product development. Elucidate the pathophysiology of mustard agents in previously developed in vitro and in vivo models. Explore additional modalities such as pharmacogenomically-based drugs and complement blockade. Complete initial efficacy studies of STIMAL against HD. Conduct detailed studies on the inhalation of mustards (bis-2-CEES) to determine if oxidative stress is a significant part of the pathophysiology.
<u>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</u> Evaluate cyanide toxicity using an inhalation model. Investigate efficacy of sulfur donors and methemoglobin formers as cyanide pretreatment.	<u>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</u> Evaluate cyanide toxicity using an inhalation model. Investigate efficacy of sulfur donors and methemoglobin formers as cyanide pretreatment.
<u>Chemical Warfare Agent Defense, Inhalation</u>	<u>Chemical Warfare Agent Defense, Inhalation</u>

FY2004 Targets	Actual Performance
<p><u><i>Therapeutics</i></u> Screen clinically available drugs for potential efficacy against HD using the mouse model.</p> <p><u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Initiate development of diagnostic applications for miniaturized mass spectrometer. Develop diagnostics that can be used to diagnose exposure via respiratory route. Refine analytical methods to measure scopolamine levels in blood and tissue. Investigate applicability of ocular device for self-examination of pupillary response.</p> <p><u><i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i></u> Pursue development of screening procedures for the evaluation of decontaminants using analytical techniques and animal models. Determine the extent that HD forms a reservoir in skin using pig and hairless guinea pig skin models.</p>	<p><u><i>Therapeutics</i></u> Screen clinically available drugs for potential efficacy against HD using the mouse model.</p> <p><u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Initiate development of diagnostic applications for miniaturized mass spectrometer. Develop diagnostics that can be used to diagnose exposure via respiratory route. Refine analytical methods to measure scopolamine levels in blood and tissue. Investigate applicability of ocular device for self-examination of pupillary response.</p> <p><u><i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i></u> Pursue development of screening procedures for the evaluation of decontaminants using analytical techniques and animal models. Determine the extent that HD forms a reservoir in skin using pig and hairless guinea pig skin models.</p>

3.5.3.5 TC2 Future Targets

FY 2005 Targets	FY 2006 Targets
<p><u><i>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</i></u> Screen anti-cyanide compounds for efficacy.</p>	<p><u><i>Cyanide Pretreatments</i></u> Select at least two best anti-cyanide compounds for efficacy studies. Determine toxicity using in vitro model systems. Determine pharmacokinetics of an in vivo assay system.</p>
<p><u><i>Nerve Agent, Bioscavengers</i></u> Complete development of transgenic animal models that can produce sufficient amounts of recombinant enzyme scavengers for clinical trials. Complete feasibility testing of vector/gene combinations to validate the concept of gene therapy for bioscavengers. Continue pretreatment intervention studies of vectors to deliver bioscavenger genes.</p>	<p><u><i>Nerve Agent, Bioscavengers</i></u> Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Develop genetic knock-out murine animal models for catalytic bioscavenger studies (Block II). Evaluate different delivery systems for administration of recombinant and/or catalytic bioscavengers in vivo (Block II). Purify sufficient h-BuChE (Block I) for animal safety and efficacy proof-of-concept. Develop procedures and systems for large scale purification of recombinant bioscavengers (Block II). Produce the h-BuChE scavenger (Block I) under current Good Manufacturing Practice (cGMP) conditions in sufficient quantity for future phase I safety trials in human subjects. Develop in vivo transgenic animal models to evaluate therapeutics approaches for human plasma derived butyrylcholinesterase. Expand the evaluation of human protein catalytic scavengers.</p>
<p><u><i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i></u> Evaluate efficacy of combinations of midazolam with selected anticholinergic compounds against nerve agent seizures in rodent (guinea pig) and, if relevant, non-human primate models. Develop analytical method to detect therapeutic levels of scopolamine in blood and tissue. Continue to develop a method to directly assay atropine levels in blood.</p>	<p><u><i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i></u> Maintain a tech-watch of new anticonvulsant compounds and evaluate their efficacy against nerve agent-induced seizures using in vivo screening models. Determine efficacy of midazolam -- and/or anticholinergic drug combinations -- against seizures and lethality produced by all current threat agents in rodent (guinea pig) model.</p>
<p><u><i>Nerve Agent Defense, Neuroprotection</i></u> Test putative neuroprotectants in at least one and</p>	<p><u><i>Nerve Agent Defense, Neuroprotection</i></u> Investigate long-term neuroprotective strategies against</p>

FY 2005 Targets	FY 2006 Targets
possibly more than one animal species. Investigate potential markers for neuroprotectant effects, eg., EEG power spectrum, Pulse oximetry, Neuroimaging. Develop and validate a neurobehavioral model for change in ability to carry out complex behavior after recovery from nerve agent toxicity.	the neurotoxic effects of acetylcholinesterase inhibitors.
<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Complete assay development and stability studies. Complete the identification and characterization of a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.	<u>Nerve Agent Defense, Improved Oxime</u> Expand screening of novel compounds for evaluation against next generation of chemical threats.
<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Collate available industrial documentation. Strengthen technology transfer mechanisms. Develop in vivo/in vitro models. Procure compounds for screening modules. Initiate screening procedures. Prioritize screened compounds. Select compounds for further safety and efficacy evaluation.	<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Determine in rodents the safety and efficacy of selected compounds. Initiate efforts to develop biological tissue assays for selected compounds.
<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Complete development of a superficial dermal vesicant injury model in weanling pigs. Begin development of a sulfur mustard cutaneous wound healing model using African green monkeys. Complete development of an in vitro wound healing model to screen pharmacological interventions for the effective treatment of cutaneous sulfur mustard injuries.	<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Complete development of a sulfur mustard cutaneous wound healing model using African green monkeys. Develop a hybrid sulfur mustard-thermal burn model using weanling pigs. Utilize an in vitro wound healing model to screen pharmacological interventions for the effective treatment of cutaneous sulfur mustard injuries.
<u>Chemical Warfare Agent Defense, Inhalational Therapeutics</u> Identify and solicit for scientifically plausible animal and non-animal exposure models to investigate mechanisms of toxicity on pulmonary related function and to establish in-house and collaborative research programs within the confines of the approach.	<u>Chemical Warfare Agent Defense, Inhalation Therapeutics</u> Initiate experimentation in the areas of interest (stated above) by establishing exposure/effects models from in vitro to in vivo systems by addressing a commonality of response/effects, i.e., identify a common response effect regardless of inhaled toxicant.
<u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Evaluate the ability of Sandia foam combined with wetting solutions to extract agent from under the skin and extend the time delay for effective decontamination against nerve agents, blister agents, and non-traditional agents (NTAs). Compare efficacy of RSDL with other leading skin decontamination products on skin challenge with HD, VX, and non-traditional agents (NTA). Demonstrate the proof-of-concept for developing a decontaminating skin product that can be applied before or after exposure. Evaluate the effectiveness of RSDL and other leading decontamination products on skin that active Topical Skin Protectant (aTSP) was applied prior to CWA. Begin developing a skin decontamination formulation that can be used in and around the eyes and wounds.	<u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Select a replacement for the M291 SDK. Evaluate the ability of new commercial skin decontamination formulations to remain effective even after long time delays. Continue development of a decontaminating skin product that can be applied before or after exposure. Continue development of a decontaminating skin product that can be used in and around the eyes and wounds. Begin development of an improved product for patient decontamination.
<u>Diagnostic Technologies</u> Perform applied research experiments aimed at	<u>Diagnostic Technologies</u> Continue applied research experiments aimed at

FY 2005 Targets	FY 2006 Targets
developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Initiate additional experiments focusing on detecting sulfur mustard exposure. Validate WRAIR cholinesterase assay. Continue development of alternate sample collection/extraction technology.	developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Pursue experiments focused on detecting sulfur mustard exposure. Develop an automation/high throughput strategy for WRAIR cholinesterase assay. Accelerate development of alternate sample collection/extraction technology for CWA.
<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> Evaluate the effectiveness of anticonvulsants against seizures produced by NTAs, in vivo persistence of NTAs, and current medical countermeasures against NTAs. Conduct evaluation of respiratory dynamics and lung biochemistry.	
<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assess VX nerve agent and HD-induced changes in respiratory function produced by low-dose exposures of varying duration. Complete assessments of the short-term effects of VX nerve agent on higher order behavioral tasks in non-human primates following a range of low-dose exposures for varying durations to improve estimates of impact on human operational readiness. Complete assessments of the effects of current CWA treatments on toxicity at low doses of exposure.	

3.5.3.6 Assessment of Medical Chemical Defense Applied Research. Applied research efforts in FY04 for project TC2 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY04.

3.6 ADVANCED TECHNOLOGY DEVELOPMENT (PROGRAM ELEMENT 0603384BP)

This program element demonstrates technologies that enhance the ability of U.S. forces to defend against, and survive CB warfare. This PE funds advanced technology development for Joint Service and Service-specific requirements in both medical and non-medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as countermeasures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non-medical area, the focus is on demonstrations of CBRN defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD CBRN defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Work conducted under this PE transitions to and provides risk

reduction for Advanced Component Development and Prototypes (PE 0603884BP) and System Development and Demonstration (PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/CW attack. This program is dedicated to conducting proof-of-principle field demonstrations, and tests of system-specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This program element demonstrates technologies that enhance the ability of U.S. forces to defend against, and survive CBRN warfare. This program element (PE) funds advanced technology development for Joint Service and Service-specific requirements in both medical and non-medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as countermeasures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non-medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD CBRN defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Also research efforts are planned to evaluate technologies for Weapons of Mass Destruction Civil Support Teams (WMD-CSTs). Work conducted under this PE transitions to and provides risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated BW operational awareness, and the restoration of operations following a CBRN attack. This program is dedicated to conducting proof-of-principle field demonstrations, and tests of system-specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This project demonstrates technology advancements for Joint Service application in the areas of chemical and biological agent detection and identification, decontamination, and individual/collective protection, which will speed maturing of advanced technologies to reduce risk in system-oriented Advanced Component Development and Prototypes efforts. This project funds the Joint Service Family of Decontamination Systems (JSFDS) Program, the Joint Service Sensitive Equipment Decontamination (JSSED) Program, the Joint Chemical/ Biological Agent Water Monitor (JCBAWM), the Joint Biological Standoff Detection System (JBSDS), the Joint Service Wide Area Detector (JSWAD), and Joint Operational Effects Federation (JOEF).

3.6.1.1 CB3 Performance Goal (Outcome). The goal of the CB defense non-medical advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the detection, protection against, and decontamination of CBRN agents.

3.6.1.2 CB3 Outcome Measure

CB3 is minimally effective when	CB3 is successful when
<ul style="list-style-type: none"> • The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: <ul style="list-style-type: none"> – Advanced materials for individual protection, – Detection of chemical and biological contamination, – Decontamination of sensitive equipment, – Early warning chemical and biological detection capabilities • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> • Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs rated GREEN by the TARA panel

3.6.1.3 Metric Description. The metric for CB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes A–D of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.1.4 CB3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u>Stand-off, Sensor Assessment Non-Traditional Agents (NTA)</u> - Continue development of spectral database. Initiate enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs.	<u>Stand-off, Sensor Assessment Non-Traditional Agents (NTA)</u> Continued development of spectral database. Initiated enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs.
<u>Chemical/Biological Agent Water Monitor (DTO CB37)</u> - Detection of Agent in Water - Initiate limited utility assessment to demonstrate technology. Develop assessment criteria and initiate a prototype design and build for the assessment.	<u>Chemical/Biological Agent Water Monitor (DTO CB37)</u> Initiated limited utility assessment to demonstrate technology. Developed assessment criteria and initiated a bio prototype design and build for the assessment. Completed Milestone A for bio portion of program. This DTO supported Joint Chemical Biological Agent Water Monitor (JCAWM) and addressed Baseline Capability Assessment for Chemical Agent Point Detect - Lack of detection for solids and liquids; priority number 31.
<u>Lightweight Integrated CB Detection (DTO CB50)</u> - Complete evaluation and continued development of DOE's micro chem lab to include bio threats. Initiate the evaluation of the pyrolysis-GC-IMS system and a trade off study to downselect the appropriate system concept to meet the Joint Modular CB Detection requirements.	<u>Lightweight Integrated CB Detection (DTO CB50)</u> Completed evaluation and continued development of DOE's micro chem lab to include bio threats. Initiated the evaluation of the pyrolysis-GC-IMS system and a trade off study to downselect the appropriate system concept to meet modular CB detection requirements. This DTO supported Baseline Capability Assessment for Integrated Early Warning - Limited sensor interface; priority number three and Integrated Early Warning - Lack of selective alarm; priority number four.
<u>Individual Protection, Clothing Non Traditional Agent (NTA)</u> - Identify appropriate simulant chemicals for NTA aerosols when testing protective clothing layers and systems. Determine the effects of water phase in protective clothing layers on protection against NTA simulants.	<u>Individual Protection, Clothing Non Traditional Agent (NTA)</u> Identified simulant chemicals for NTA aerosols when testing protective clothing layers and systems. Determined the effects of water phase in protective clothing layers on protection against NTA simulants. Characterized a number of materials and material systems for NTA protection.

FY2004 Targets	Actual Performance
<p><u><i>Decontamination, Oxidative Formulation (DTO CB44)</i></u></p> <p>Demonstrate products with existing applicator systems. Modify or develop alternative applicators. Conduct basic integration of products into a "simulated environment". Extend test bed to include multiple agents and NTAs. Conduct robust chamber studies using full-scale conceptual system testing with live agents.</p>	<p><u><i>Oxidative Formulation (DTO CB44)</i></u></p> <p>Decontamination -Completed demonstration of products with existing applicator systems and determined suitability for peroxide systems. Modified and developed alternative applicators. Completed basic integration of products into a "simulated environment". Extended test bed to include multiple agents and NTAs. The DTO supported the Joint Tactical Decontamination Systems (JSTD) and addressed Baseline Capability Assessment for Equipment Decon - Decontaminants and applicators degrade equipment; priority number 18, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, and Fixed Site Decontamination – Applicators degrade equipment, facilities, and material; priority number 34</p>
<p><u><i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i></u> - Preparation for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Complete the first phase of independent verification of software. Baseline RESTOP ACTD results as model validation. Deliver airbase representation module and generic airbase module to the Defense Threat Reduction Agency.</p> <p><u><i>Planning, Training, and Analysis</i></u> - Transition of STAFFS model to JOEF. Integration support putting NBC CREST and impact models into JOEF.</p>	<p><u><i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i></u></p> <p>Tested and finalized APOD and SPOD representation. Defined CASPOD data requirements. Populated SPOD representation. Prepared for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Completed the first phase of independent verification of software. Began module definition and design for marine Expeditionary Force HQ, depot, and railroad modules. This DTO supported Baseline Capability Assessment for Battle Space Management - Lack of automated decision tools; priority number eight and Battle Space Management - Lack of interface with the COP; priority number nine. Completed the transition of STAFFS model to the Joint Operational Effects Federation (JOEF). Supported integration of NBC CREST and impact models into JOEF. This DTO supported Baseline Capability Assessment for Battle Space Management - Lack of automated decision tools; priority number eight and Battle Space Management - Lack of interface with the COP; priority number nine.</p>
<p><u><i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i></u> - Transition advanced predictive capabilities (MESO) to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging.</p>	<p><u><i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i></u></p> <p>Transitioned advanced predictive capabilities (MESO) to Joint Effects Model (JEM) program. Enhanced the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. This DTO supported Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of Analysis Tools; priority number six.</p>
<p><u><i>Simulation Based Acquisition</i></u> - Initiate investigation of prototype software development requirements to meet performance specifications for a Virtual Prototyping System (VPS) that would support acquisition of CB defense end items to protect a variety of installations/facility types. If resources allow, and an affirmative decision is made, prototyping efforts would</p>	<p><u><i>CBDP Decision Capability (formerly Simulation Based Acquisition)</i></u></p> <p>Initiated investigation of prototype software development requirements to meet performance specifications for an analysis and virtual prototyping capability that would support acquisition of CB defense end items to protect a variety of installations/facility</p>

FY2004 Targets	Actual Performance
begin in this fiscal year.	types. Developed an investment plan for the near term to build the rapid analysis capability.
<u>Point Detection, Biological Identification</u> - Initiate development of an automated system to populate a biomarkers database system based on Mass Spec analysis.	<u>Point Detection, Biological Identification</u> Initiated development of an automated system to populate a biomarkers database system based on Mass Spec analysis
<u>Chemical and Biological Detectors</u> - Develop technologies for chemical and biological detectors.	<u>Chemical and Biological Detectors</u> Developed technologies for chemical and biological detectors
<u>Countermeasures to Biological and Chemical Threats Response</u> - Explore and evaluate technologies for countermeasures to biological and chemical threats response.	<u>Countermeasures to Biological and Chemical Threats Response</u> Explored and evaluated technologies for countermeasures to biological and chemical threats response.
<u>Handheld Biological Agent Detection System</u> - Evaluate technologies for handheld biological agent detection system.	<u>Handheld Biological Agent Detection System</u> Evaluated technologies for handheld biological agent detection system.
<u>Innovative Materials for MEMS Fabrication</u> - Explore technologies for innovative materials for MEMS fabrication.	<u>Innovative Materials for MicroElectroMechanical Systems (MEMS) Fabrication</u> Explored technologies for innovative materials for MEMS fabrication.
<u>Immunochemical Bio/Chem Agent Detector</u> - Develop and validate immunochemical biological and chemical agent detector technologies.	<u>Immunochemical Bio/Chem Agent Detector</u> Developed and validated immunochemical biological and chemical agent detector technologies.
<u>Bio-MEMS</u> - Develop and validate bio-MEMS technologies.	<u>Bio-MEMS</u> Developed and validate bio-MEMS technologies.
<u>Vaporized Hydrogen Peroxide Tech for Decontamination</u> - Develop and validate vaporized hydrogen peroxide technologies for decontamination.	<u>Vaporized Hydrogen Peroxide Tech for Decontamination</u> Developed and validated vaporized hydrogen peroxide technologies for decontamination.
<u>Technical Readiness Evaluation (TRE)</u> - Conduct TREs of point and stand-off CB detection systems. Conduct stirred reactor, contact hazard, and off gas testing on emerging decontaminants not tested previously.	<u>Technical Readiness Evaluation (TRE)</u> Conducted TREs of point and stand-off CB detection systems. Conducted stirred reactor, contact hazard, and off gas testing on emerging decontaminants not tested previously.
<u>Technical Transition</u> - Complete development of integrated UV MALDI-TOF and IR MALDI-TOF mass spectrometers. Complete catalytic oxidation filtration device. Complete evaluation of MAGIChip. Continue assessment of technologies in detection, decontamination, and filtration from other government agency programs.	<u>Technical Transition</u> Completed development of integrated UV MALDI-TOF and IR MALDI-TOF mass spectrometers. Completed catalytic oxidation filtration device. Complete evaluation of MAGIChip. Continued assessment of technologies in detection, decontamination, and filtration from other government agency programs.
<u>Rapid Response Database Center</u> - Develop and validate rapid response database.	<u>Rapid Response Database Center</u> Developed and validated rapid response database.
<u>Reactive Air Purification</u> - Explore reactive air purification technologies.	<u>Reactive Air Purification</u> Explored reactive air purification technologies.
<u>High Intensity Pulsed Radiation Facility for CB Agent Defeat</u> - Explore technologies for a high intensity pulsed radiation facility for CB agent defeat.	<u>High Intensity Pulsed Radiation Facility for CB Agent Defeat</u> Explored technologies for a high intensity pulsed radiation facility for CB agent defeat.
<u>Sensor Net/CBRN Threat using Public and Private Assets</u> - Develop and validate technologies for sensor net/CBRN threat using public and private assets.	<u>Sensor Net/CBRN Threat using Public and Private Assets</u> Developed and validated technologies for sensor net/CBRN threat using public and private assets.

FY2004 Targets	Actual Performance
<u>Rapid Response Sensor Networking</u> - Evaluate technologies for rapid response sensor networking	<u>Rapid Response Sensor Networking</u> Evaluated technologies for rapid response sensor networking.
<u>Chem-Bio Defense Initiative</u> - Develop multiple technologies and methodologies for the rapid detection of, and protection from biological agents utilizing both point and stand-off platforms.	<u>Chem-Bio Defense Initiative</u> Developed multiple technologies and methodologies for the rapid detection of, and protection from biological agents utilizing both point and stand-off platforms.

3.6.1.5 CB3 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>Hot Lightweight Chemical Detector (LCD)</u> Characterize and assess the performance of a breadboard (heated inlet version of the UK fielded LCD) against NTAs and traditional agents. The breadboard assessment will be the basis for the design and build of a prototype. The performance of the prototype will be assessed for transition suitability to the acquisition program Joint Chemical Agent Detector (JCAD).	
<u>Testing and Evaluation (T&E) for Non-Traditional Agents</u> Initiate development of Agent to Simulant correlations in support of detection T&E needs. Analytical studies on the impact of threat environments on the properties of neat agents. Develop facility for detector testing of NTAs.	<u>Testing & Evaluation for Non-Traditional Agents</u> Continue the development of agent to simulant correlations in support of T&E needs. Initiate the studies necessary to fill the identified gaps from the analytical studies on the impact of threat environments on the properties of neat agents. Priority will be for biological materials followed by chemical materials.
<u>Lightweight Integrated CB Detection (DTO CB50)</u> Downselect technologies to the best two or three approaches. Prepare preliminary design concepts based on these approaches. This DTO supports Baseline Capability Assessment for Integrated Early Warning - Limited sensor interface; priority number three and Integrated Early Warning - Lack of selective alarm; priority number four.	<u>Lightweight Integrated CB Detection (DTO CB50)</u> Assess ability of technology to meet JMCBDS requirements and as technology insertion for Joint Biological Point Detection System and Reconnaissance Systems as enhancements/replacement for the biological trigger systems. The technology will also meet the need to detect/identify chemical aerosols. Design brassboard. Initiate fabrication of brassboards. This DTO supports Baseline Capability Assessment for Integrated Early Warning - Limited sensor interface; priority number three and Integrated Early Warning - Lack of selective alarm; priority number four.
<u>Chemical/Biological Agent Water Monitor (DTO CB37)</u> Complete prototype build for bio detection requirements and assessment methodology. Continue development of chemical detection portion of the program with an objective of a Milestone A in FY06. This DTO supports Joint Chemical Biological Agent Water Monitor (JCBAWM) and addresses Baseline Capability Assessment for Chemical Agent Point Detect - Lack of detection for solids and liquids; priority number 31	<u>Chemical/Biological Agent Water Monitor (DTO CB37)</u> Complete the development of the chemical detection portion of the requirements. Demonstrate and conduct a Milestone A at the end of FY06 on the chemical requirements. Complete, demonstrate, and conduct a Milestone B for the advanced prototype for the biological detection requirements by the end of FY06. The DTO supports the Joint Chemical Biological Agent Water Monitor (JCBAWM) and addresses Baseline Capability Assessment for Chemical Agent Point Detect - Lack of detection for solids and liquids; priority number 31.
<u>Point Detection, Biological Identification</u> Complete prototype build for an antibody multiplex assay system with reader to reduce consumable cost for JBPDS. Initiate micro-array concept for high throughput laboratory bio detection/identification. 2000	<u>Point Detection, Biological Identification</u> Complete and demonstrate micro-array system for high throughput laboratory bio detection/identification. Demonstrate the prototype for an antibody multiplex assays system for Joint Biological Point Detection

FY 2005 Targets	FY 2006 Targets
LISA Prototype - Assess the performance of the first generation detection algorithm under operational environments. Develop the second generation detection algorithm based on the assessed shortfalls of the first generation algorithm. Support transition of technology into Chemical Unmanned Ground Reconnaissance (CUGR) ACTD.	System technology insertion.
<u>System Performance Modeling</u> Conduct analytical feasibility studies on the technical parameters in the detection of CB contamination on surfaces in post decontamination applications. Initiate the development of databases containing spectral IR backgrounds suitable for standoff applications (includes imaging techniques). Conduct analytical feasibility studies on the minimum acceptable technical parameters for a stand-alone low cost/low power biological trigger system for early warning.	<u>System Performance Modeling</u> Complete the database development of IR spectral backgrounds. Conduct an analytical feasibility study to determine the minimal performance parameters needed for a standoff biological detection system for on-the-move capability for a mobile platform like Stryker.
<u>Technical Transition</u> Conduct competitive assessment of all mature mass spectrometric biodetection approaches. Complete assessment of selected technologies in detection, decontamination, and protection from other government agency programs identified for evaluation in previous FY.	
<u>Individual Protection, Clothing</u> Prepare and evaluate carbon-loaded fabric with nanofiber and/or membrane backing in wide widths suitable for fabrication into prototype garments, incorporating novel closure systems. Develop and evaluate the performance of a prototype intermittent Micro Climate Cooling Systems (MCS) vapor compression component. Develop advanced closure concepts, develop and assess conceptual models, and fabricate prototypes of best candidates. Develop swatch test technology for assessing role of wind speed in challenge penetration of IPE.	<u>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</u> Manufacture prototype garments. Demonstrate activity of treated fabric systems. Measure chemical/aerosol breakthrough of garments. Conduct field testing. Collect user assessments. Field test biocidal treated ensemble for durability and persistence of reactivity. Conduct CWA simulant and live CWA testing on worn garments to assess durability. Develop transition plan. This DTO supports the Joint Expeditionary Collective Protection (JECP) program which addressed Baseline Capability Assessment (BCA) Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary COLPRO - Correct quantity shortfalls; priority number 25. This DTO also supports the current Joint Service Lightweight Integrated Suit Technology program.
	<u>Individual Protection, Masks</u> Initiate efforts to integrate technologies identified in the FY05 Technology Studies into future mask systems.
<u>Collective Protection, Filtration</u> Characterize and optimize performance of advance aerosol/particulate removal processes providing enhanced protection. Minimize the deleterious effects of adsorbents possessing volatile and non-volatile reactive chemicals. Assess impact of pollutants on aerosol/particulate filters. Develop regenerative filtration advanced technology demonstrators based upon temperature swing adsorption and electrical swing adsorption approaches and integration with environmental control units. Advance the developed	<u>Advanced Air Purification System Model (DTO CB61)</u> Configure laboratory scale systems, define test and evaluation methodology, and measure the required design and system integration data. Develop initial version of Advanced Air Purification System Model and measure laboratory scale design and application integration data to evaluate model. This DTO supports the Joint Expeditionary Collective Protection (JECP) program and addresses Baseline Capability Assessment for Expeditionary COLPRO - Size, power, and weight limitations; priority number 11 and Expeditionary

FY 2005 Targets	FY 2006 Targets
residual life indicator hardware and initiate chemical pulsing concepts to probe filter reactive chemistry capacity.	COLPRO – Correct quantity shortfalls; priority number 25.
<u>Decontamination, Oxidative Formulation (DTO CB44)</u> Conduct safety, health and environmental studies. Complete live agent chamber testing and determine which candidates meet efficacy requirements. Demonstrate limited operational utility of downselected decontaminants and associated applicators using simulant field trials in relevant environments, and determine which candidates meet efficacy and operational requirements. Prepare IPR packages. Complete DTO and transition. This DTO supports the Joint Tactical Decontamination Systems (JSTDs) and addressed Baseline Capability Assessment for Equipment Decon - Decontaminants and applicators degrade equipment; priority number 18, Equipment Decontamination - Inadequate processing rate for thorough decontamination; priority number 23, and Fixed Site Decontamination - Applicators degrade equipment, facilities, and material; priority number 34.	
	<u>Collective Protection, Shelters</u> Initiate the transition of emerging shelter technologies into future shelter systems.
<u>Chemical and Biological Hazard Environment Prediction (DTO CB55)</u> Transition advanced predictive capabilities (MESO) to Joint Effects Model (JEM) Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. DTO supports Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of Analysis Tools; priority number six.	<u>Chemical and Biological Hazard Environment Prediction (DTO CB55)</u> Transition advanced predictive capabilities (MESO) to Joint Effects Model (JEM) Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. DTO supports Baseline Capability Assessment for Battle Space Analysis - Lack of hazard assessment tools; priority number five and Battle Space Analysis - Lack of Analysis Tools; priority number six.
<u>Chemical and Biological Warfare Effects on Operations (DTO CB43)</u> Test and finalize for transition to Joint Operational Effects Federation (JOEF) Block 2. Transition mobile forces modules. Perform internal Verification and Validation. DTO supports Baseline Capability Assessment for Battle Space Management - Lack of automated decision tools; priority number eight and Battle Space Management - Lack of interface with the COP; priority number nine.	
<u>Battlespace Management</u> Develop the Shared Common Operating Picture (COP) in support of Joint Warning and Reporting Network (JWARN).	<u>Battlespace Management</u> Transition end-items to Joint Effects Model (JEM), Joint Operational Effects Federation (JOEF), Joint Warning and Reporting Network (JWARN), and Joint Program GUARDIAN Installation Protection Program, as applicable. Perform analytic excursions in support of CBDP with Decision Capability.
<u>Technical Readiness Assessment</u> Conduct Technology Readiness Evaluations (TRE) of point and stand-off CB detection systems. Conduct	

FY 2005 Targets	FY 2006 Targets
stirred reactor, contact hazard and off gas testing on emerging decontaminants not tested previously	
<u>Stand-off, Sensor Assessment Non-Traditional Agent (NTA)</u> Complete spectral database of NTAs. Complete enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs. The assessment will be used to develop a cost-benefit analysis on the value and potential to upgrade either fielded or developmental systems to detect and identify NTAs.	

3.6.1.6 Assessment of Chemical and Biological Defense Advanced Technology

Development. Advanced Technology Development efforts in FY04 for project CB3 were effective. Many areas of CB defense advanced technology development were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. Extensive development continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY04.

3.6.3 Counterproliferation Support Advanced Technology Development (Project CP3)

The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD deployed capability to defend against and counter the proliferation of WMD. By focusing on near term results, the CP accelerates delivery of new tools, equipment, and procedures to combat forces. Under the passive defense pillar, CP enhances the efforts of the Chemical and Biological Defense Program. This project funds a variety of programs to defend our forces against WMD, such as the Biological Detection (BIODET), Biological Non-Systems (BIO Non Sys) efforts, Critical Reagents Program (CRP), Restoration of Operations (RESTOPS) and a Planning and Development for Advanced Concept Technology Demonstrations.

3.6.3.1 CP3 Performance Goal (Outcome). The goal of the counterproliferation support advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

3.6.3.2 CP3 Outcome Measure

CP3 is minimally effective when	CP3 is successful when
<ul style="list-style-type: none"> The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: <ul style="list-style-type: none"> – Biological detection systems. – Critical reagents for biological detection and identification. The results of research are published in peer-reviewed journals or presented at scientific conferences. Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed. 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development. All DTOs are rated GREEN by the TARA.

3.6.3.3 Metric Description. The metric for CP3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the Contamination Avoidance as Sea Ports of Debarkation (CASPOD) ACTD.

3.6.3.4 CP3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u>ACTD-PD</u> Perform technology demonstrations and maturity evaluation on Contaminated Surface Detector (CSD) in preparation for the CUGR ACTD in FY05.	<u>ACTD-PD</u> Performed technology demonstrations and maturity evaluation on the Joint Contaminated Surface Detector (JCSD) in preparation for the CUGR ACTD in FY05. CASPOD ACTD transitioned to CP4 in FY04 for final demonstration and preparation for initial year of residual support in FY05.
<u>ACTD-PD</u> Develop CONOPS and procedures for Biological Warfare fusion cell for the Biological Warfare Countermeasures Initiative (BWC) Counter Bio project in preparation for United States Pacific Command (PACOM) FY05 demonstration.	<u>ACTD-PD</u> Developed CONOPS and procedures for Biological Defense fusion cell for the Biological Warfare Countermeasures Initiative (BWC) Counter Bio project in preparation for United States Pacific Command (PACOM) FY05 demonstration.

3.6.3.5 CP3 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>ACTD-PD</u> Initiate technology maturity evaluations for selection of technologies for future ACTD candidates.	
<u>ACTD-PD</u> Initiate the Military Applications in Reconnaissance and Surveillance (MARS) -Unmanned Ground Vehicle (UGV) program testing CBRN detection technologies for use on one man and two man portable UGVs for technology insertion into the CUGR ACTD or the transition program for CUGR ACTD's UGV portion.	

3.6.3.6 Assessment of Counterproliferation Support Advanced Technology Development.

Advanced Technology Development efforts in FY04 for project CP3 were effective.

3.6.4 Medical Biological Defense Advanced Technology Development (Project TB3)

This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for pre- and post- exposures to biological threat agents. This project also supports the advanced technology development of diagnostic devices to rapidly diagnose exposure to biological agents in clinical samples. A broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures and diagnostic systems is evaluated so that the most effective countermeasures are identified for transition to Advanced Development. Transitioning candidate vaccines, therapeutics, and diagnostic technologies to Advanced Development requires the development of scientific/ regulatory technical data packages to support the Food and Drug Administration (FDA) Investigational New Drug (IND) process and DoD acquisition regulations. Categories for this project include Defense

Technology Objectives (DTOs); science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines), directed research efforts (Bioadhesion Research, Medical Chemical/ Biological Counterterrorism Support, Medical Countermeasures, Advanced Diagnostics, and Vaccines); and efforts to transition promising medical biological defense technologies from DARPA.

3.6.4.1 TB3 Performance Goal (Outcome). The goal of the medical biological defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for BW agents.

3.6.4.2 TB3 Outcome Measure

TB3 is minimally effective when	TB3 is successful when
<ul style="list-style-type: none"> The results provide fundamental information and demonstrates advanced capabilities in support of new and improved defensive systems, including: <ul style="list-style-type: none"> Bacterial Therapeutics, Toxin Vaccines, Bacterial Vaccines, Toxin Therapeutics, Viral Therapeutics, Viral Vaccines, Diagnostic Technologies, and Protocols to Enhance Biological Defense. The results of research are published in peer-reviewed journals or presented at scientific conferences Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Information, technologies, or processes are transitioned to applied research or advanced technology development All DTOs are rated GREEN by the TARA

3.6.4.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.4.4 TB3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<i>Therapeutics, Bacterial</i> Continue the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in small animal models.	<i>Therapeutics, Bacterial</i> Continued the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in small animal models.
<i>Therapeutics, Toxin</i> Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for SE intoxication. Test FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo. <i>Therapeutics, Viral</i> - Complete the evaluation of one antiviral drug formulation for orthopox viruses. Continue evaluating second drug formulation or prodrugs for orthopox viruses.	<i>Therapeutics, Toxin</i> Standardized in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for SE intoxication. Tested FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo.
<i>Therapeutics, Viral, Therapy for Smallpox and Other</i>	<i>Therapeutics, Viral, Therapy for Smallpox and Other</i>

FY2004 Targets	Actual Performance
<u><i>Pathogenic Orthopox Viruses (DTO CB54)</i></u> Complete the assessment of the clinical study site to determine feasibility for use in a field trial of cidofovir to treat human monkeypox. Complete an initial dose seeking study using an oral form of cidofovir in the monkeypox primate model.	<u><i>Pathogenic Orthopox Viruses (DTO CB54)</i></u> Completed the assessment of the clinical study site to determine feasibility for use in a field trial of cidofovir to treat human monkeypox. Completed an initial dose seeking study using an oral form of cidofovir in the monkeypox primate model.
<u><i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i></u> Initiate ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum neurotoxin (BoNT) intoxication.	<u><i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i></u> Initiated ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardized in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum neurotoxin (BoNT) intoxication.
<u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Determine the basis for the pathogenesis of filovirus-induced shock or toxemia in animal models and identify potential mediators.	<u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Determined the basis for the pathogenesis of filovirus-induced shock or toxemia in animal models and identify potential mediators. <u><i>Therapeutics, Viral</i></u> Completed the evaluation of one antiviral drug formulation for orthopox viruses. Continued evaluating second drug formulation or prodrugs for orthopox viruses.
<u><i>Diagnostic Technologies</i></u> Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Continue to compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program.	<u><i>Diagnostic Technologies</i></u> Continued to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Continued to compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continued to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program.
<u><i>Diagnostic Technologies, Improved Immunodiagnostics Platform (DTO CB47)</i></u> Complete interlaboratory evaluation of top performing immunodiagnostic technology option. Perform a multi-center evaluation trial of the top performing immunodiagnostic platform and prepare a technical data package detailing results of the multi-center trial. Recommend immunodiagnostic technologies for incorporation into JBAIDS acquisition program.	<u><i>Diagnostic Technologies, Improved Immunodiagnostics Platform (DTO CB47)</i></u> Completed interlaboratory evaluation of top performing immunodiagnostic technology option. Performed a multi-center evaluation trial of the top performing immunodiagnostic platform and prepare a technical data package detailing results of the multi-center trial. Recommended immunodiagnostic technologies for incorporation into JBAIDS acquisition program.
<u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u> Develop a technical data package format for delivering assays and reagents, in concert with the advanced developer.	<u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u> Developed a technical data package format for delivering assays and reagents, in concert with the advanced developer.
<u><i>Vaccines, Bacterial</i></u> Continue to perform animal studies which support	<u><i>Vaccines, Bacterial</i></u> Continued to perform animal studies which support

FY2004 Targets	Actual Performance
transition of potential Brucella vaccine candidates to advanced development. Perform studies to address the mechanism of protective cellular immunity induced by selected vaccine candidates. Continue studies supporting rPA and recombinant plague F1-V vaccine candidates clinical trials and progress toward licensure. Complete developmental work on the mouse potency assay in support of rPA vaccine candidate advanced development.	transition of potential Brucella vaccine candidates to advanced development. Performed studies to address the mechanism of protective cellular immunity induced by selected vaccine candidates. Continued studies supporting rPA and recombinant plague F1-V vaccine candidates clinical trials and progress toward licensure. Completed developmental work on the mouse potency assay in support of rPA vaccine candidate advanced development.
<u>Vaccines, Toxin</u> Produce and characterize inactivated BoNT light chain vaccine candidates and large-scale truncations of BoNT holotoxins. Clone and express existing BoNT vaccine candidates using selected plant-based expression systems. Initiate studies exploring multivalent vaccine technologies for protection against multiple botulinum neurotoxin serotypes.	<u>Vaccines, Toxin</u> Produced and characterized inactivated BoNT light chain vaccine candidates and large-scale truncations of BoNT holotoxins. Cloned and expressed existing BoNT vaccine candidates using selected plant-based expression systems. Initiated studies exploring multivalent vaccine technologies for protection against multiple botulinum neurotoxin serotypes.
<u>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</u> Propose formulation/device/route for delivery of combinations of multiple recombinant proteins. Perform definitive efficacy studies on monovalent vaccine in second animal model. Evaluate in vitro correlate of immunity.	<u>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</u> Propose formulation/device/route for delivery of combinations of multiple recombinant proteins. Perform definitive efficacy studies on monovalent vaccine in second animal model. Evaluate in vitro correlate of immunity.
<u>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</u> Complete toxicity assays, activity assays, and rodent efficacy studies for lead recombinant ricin toxin A-chain (rRTA) vaccine candidates. Conduct laboratory stability studies of the lead rRTA candidate. Evaluate lead candidate with in vitro models for vascular leak syndrome. Conduct efficacy studies in non-human primates with the lead rRTA vaccine candidate.	<u>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</u> Completed toxicity assays, activity assays, and rodent efficacy studies for lead recombinant ricin toxin A-chain (rRTA) vaccine candidates. Conducted laboratory stability studies of the lead rRTA candidate. Evaluated lead candidate with in vitro models for vascular leak syndrome. Conducted efficacy studies in non-human primates with the lead rRTA vaccine candidate.
<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</u> Initiate the evaluation of candidate vaccine platforms/constructs against a minimum of one of the alphaviruses of concern (WEE or EEE) in the mouse efficacy model. Continue research for the development of live attenuated mutant viruses as vaccine candidates for EEE virus infection. Establish aerosol WEE animal efficacy models for evaluating vaccine candidates.	<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</u> Initiated the evaluation of candidate vaccine platforms/constructs against a minimum of one of the alphaviruses of concern (WEE or EEE) in the mouse efficacy model. Continued research of the development of live attenuated mutant viruses as vaccine candidates for EEE virus infection. Established aerosol WEE animal efficacy models for evaluating vaccine candidates.
<u>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u> Develop and improve animal models for evaluating vaccine candidates for protection against Ebola and Marburg viruses.	<u>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u> Developed and improved animal models for evaluating vaccine candidates for protection against Ebola and Marburg viruses.
<u>Defense Advanced Research Projects Agency (DARPA) Program Transition</u> Continue expansion and definition of medical biological defense technologies transitioned from the DARPA.	<u>Defense Advanced Research Projects Agency (DARPA) Program Transition</u> Continued expansion and definition of medical biological defense technologies transitioned from the

FY2004 Targets	Actual Performance
Complete chemical manufacturing and control studies and file an IND application for a small-molecule antibiotic effective against anthrax. Develop additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Develop a blood assay for the superantigen toxin antagonists. Optimize plant lines and obtain milligram-quantities of plague vaccine antigens from multiple plant species for in DNA shuffling in non-human primates for protection against three encephalitic alphaviruses.	DARPA. Completed chemical manufacturing and control studies and file an IND application for a small-molecule antibiotic effective against anthrax. Developed additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Developed a blood assay for the superantigen toxin antagonists. Optimized plant lines and obtain milligram-quantities of plague vaccine antigens from multiple plant species for in DNA shuffling in non-human primates for protection against three encephalitic alphaviruses.
<u>Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare</u> Continue to generate recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and continue to develop conjugated vaccine formulations. Continue to construct covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determine immunogenicity in animals. Continue to conjugate various combinations of anthrax toxins and capsular materials and determine the optimal conjugate for generating protective immune responses.	<u>Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare</u> Continued to generate recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and continued to develop conjugated vaccine formulations. Continued to construct covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determine immunogenicity in animals. Continued to conjugate various combinations of anthrax toxins and capsular materials and determine the optimal conjugate for generating protective immune responses.

3.6.4.5 TB3 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>Therapeutics, Bacterial</u> Advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Enhance aerobiology capabilities and animal model development to facilitate bacterial therapeutics research.	
<u>Therapeutics, Toxin</u> Continue proof-of-concept studies in animal models with lead compounds shown to have potential as inhibitors of SEs. Enhance aerobiology capabilities and animal model development to facilitate toxin therapeutics research.	<u>Toxin Therapeutics</u> Continue to conduct proof-of-concept studies in animal models with lead compounds shown to have potential as inhibitors of SEs. Enhance aerobiology capabilities and animal model development to facilitate toxin therapeutics research.
<u>Therapeutics, Viral</u> Finish characterization of genes identified in random homozygous knock-out screening and their evaluation as drug targets. Finish screening for inhibitors of ribonucleic acid (RNA) polymerase. Evaluate novel targets obtained from proteomic studies.	<u>Therapeutics, Viral</u> Continue evaluating new drug formulations or prodrugs for orthopox viruses. Enhance aerobiology capabilities and animal model development to facilitate viral therapeutics research. Perform dose ranging studies in primates for lead prodrug compounds for orthopox. Complete studies on short interfering RNA-mediated effects on Ebola.
<u>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Complete technical data package supporting FDA approval of a labeled indication for pre- and post-exposure treatment for smallpox with intravenous (IV) cidofovir by the drug license holder.	<u>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Perform appropriate testing in nonhuman primates for FDA licensure consideration under the FDA Animal Efficacy Rule.
<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Continue to evaluate high affinity recombinant human	<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Develop a technology from the information generated

FY 2005 Targets	FY 2006 Targets
<p>antibodies against BoNT in vivo. Develop surrogate endpoints of human clinical efficacy for BoNT therapeutics. Evaluate neuronal drug delivery systems for leading BoNT treatment modalities in vitro and ex vivo.</p> <p><u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u></p> <p>Determine therapeutic potential of candidate drugs in small animal models, including determination of the optimum dose, route and schedule (DRS) for delivery of the drug and the therapeutic window (TW, latest time treatment can be initiated).</p>	<p>from this research development plan for nonclinical studies of optimum therapeutic candidates/treatment modalities.</p> <p><u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u></p> <p>Determine the effect of treatment on viral pathogenesis in the mouse Ebola virus model or other more appropriate small animal model such as mice and guinea pigs for Marburg. Perform efficacy studies in nonhuman primate models that provide the best model for evaluation of the potential for treating filoviruses.</p>
<p><u><i>Diagnostic Technologies</i></u></p> <p>Identify an immunodiagnostic platform for transition to advanced developer. Initiate groundwork for a detailed analysis of alternatives for an advanced integrated diagnostic system capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies using a combination of appropriate technologies.</p> <p>Augment field studies of assays, reagents and platforms for the diagnosis of potential biological warfare threat agents with animal studies prior to transition to the advanced developer. Collate data on host immune response for the development of specialized gene sets. Pursue investigation of recombinant DNA technologies. Apply new technological approaches for processing clinical samples to complex matrices and different threat types. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program. Analyze clinical samples obtained from human vaccines receiving biodefense vaccines to evaluate host responses to the immunizations.</p>	<p><u><i>Diagnostic Technologies</i></u></p> <p>Continue to provide multiplexed nucleic acid and immunoassays capable of distinguishing endemic pathogens from threat agents in clinical samples. Transition to advanced developer as testing is completed. Initiate a detailed analysis of alternatives for an advanced integrated diagnostic system capable of detecting and identifying a broad range of biological threat agents in clinical specimens. Continue to augment field studies of assays, reagents and platforms for the diagnosis of potential biological warfare threat agents with animal studies prior to transition to the advanced developer. Invest in improving the sensitivity and specificity of existing assays, developing assays for new targets and new threats, as genomic data and techniques become available. Develop gene sets correlating host immune response with exposure to endemic pathogens/threat agents. Identify appropriate recombinant DNA technologies. Apply new technological approaches for processing clinical samples to complex matrices and different organisms. Continue to apply proteomics finding to the development of immunologic assays for pathogen detection. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition Continue advanced development on next generation technologies.</p>
<p><u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u></p> <p>Deliver four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four antigen detection assays and/or supporting reagents to the advanced developer. Deliver four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer.</p>	<p><u><i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i></u></p> <p>Deliver four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four antigen detection assays and/or supporting reagents to the advanced developer</p>
<p><u><i>Diagnostics Technologies, IT Medical Surveillance</i></u></p> <p>Demonstrate how to integrate medical surveillance information and potential CB threat agent information obtained through medical surveillance, with non-medical detection information; and work toward defining a draft Concept of Operations (CONOPS) for the application of these technologies.</p>	

FY 2005 Targets	FY 2006 Targets
<p><u>Defense Advanced Research Projects Agency (DARPA) Program Transition</u></p> <p>Conclude characterization and process development of candidate vaccines, therapeutics, and diagnostic technologies to determine if any are sufficiently mature to transition to development. Complete development of five additional B-cell lines. Complete development and performance testing of a 16-channel B-cell based diagnostic sensor. Establish formulation for an orally bioavailable superantigen toxin antagonist.</p>	
<p><u>Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</u></p> <p>Continue testing candidates in available animals for EEE vaccine. Determine the compatibility of V3526 and vaccine platforms in animals.</p>	<p><u>Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</u></p> <p>Continue evaluating combinations of EEE, WEE, and V3526 or alternate VEE constructs (the DNA- or replicon-based vaccine platforms) in animal models.</p>
<p><u>Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u></p> <p>Test leading vaccine candidates in animals (viral challenge dose, route, pre-existing vector immunity, and variation in viral challenge strain).</p>	<p><u>Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u></p> <p>Conduct animal models of aerosol infection with filoviruses. Continue recombinant subunit vaccine development for Ebola virus. Prepare GMP-grade candidate vaccine materials for pre-IND studies.</p>
<p><u>Vaccine Research Support</u></p> <p>Continue to perform animal studies which support clinical trials of selected vaccine candidates against bacterial threat agents. Initiate technology base studies in support of the development and eventual FDA licensure of the rPA and recombinant plague F1-V vaccine candidates. Initiate evaluation of inactivated BoNT light chain vaccine candidates as well as large-scale truncations of BoNT holotoxins in animal models. Initiate studies on multivalent vaccine candidates to protect against multiple BoNT serotypes, including cloning and expression of genes for novel multivalent vaccine candidates. Test promising vaccine strategies in higher animal species for ability to protect against filoviruses. Continue testing of next generation SEA/SEB immunogen as vaccine candidates to protect against multiple SE serotypes in vivo. Evaluate stability and immunogenicity of SEB toxin vaccine in support of clinical trial. Evaluate promising EEE/WEE vaccine candidates in higher animal species against EEE or WEE virus challenge. Evaluate poxvirus DNA vaccine.</p>	<p><u>Vaccine Research Support</u></p> <p>Evaluate animal studies which support clinical trials of selected vaccine candidates against bacterial threat agents. Continue technology base studies in support of the development and eventual FDA licensure of the rPA and recombinant plague F1-V vaccine candidates. Expand challenge studies against selected intracellular pathogen candidate vaccines and cell-mediated immunity. Evaluate studies on multivalent vaccine candidates to protect against multiple BoNT serotypes, including cloning and expression of genes for novel multivalent vaccine candidates. Proceed with evaluation of promising vaccine strategies in higher animal species for ability to protect. Evaluate next generation SEA/SEB immunogens as vaccine candidates to protect against multiple SE serotypes in vivo. Finalize stability analysis and immunogenicity of SEB toxin vaccine in support of clinical trial. Complete evaluation of promising EEE/WEE vaccine candidates in higher animal species against virus challenge. Complete evaluation of poxvirus DNA vaccine.</p>
<p><u>Vaccine Research Support, Alternate Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</u></p> <p>Demonstrate proof of concept for lead alternate vaccine delivery system(s). Complete preclinical research studies and prepare recommendations to support transition of commercial technology for alternate vaccine delivery out of the technology base.</p>	
<p><u>Vaccine Research Support, Recombinant Ricin Vaccine (DTO CB46)</u></p> <p>Complete a comprehensive review of results with lead candidate, including potency, efficacy, adjuvant studies,</p>	<p><u>Vaccine Research Support, Recombinant Ricin Vaccine (DTO CB46)</u></p> <p>Complete formulation and stability studies. Compare technical data package. Facilitate transition to advanced</p>

FY 2005 Targets	FY 2006 Targets
toxicity and pathology studies in rodents. Complete efficacy studies and pathology in higher animal species with the lead vaccine candidate.	developer.
	<i>Genetically Engineered Threats</i> Expand resequencing effort significantly. Use previously (FY05) developed microarray to determine genetic differences among various strains of <i>B. anthracis</i> . Develop novel interferon therapeutics and begin testing for effectiveness against broad spectrum viral agents.

3.6.4.6 Assessment of Medical Biological Defense Advanced Technology Development.

Advanced technology development efforts in FY04 for project TB3 are effective. Many areas of medical biological defense applied research were successful. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY04.

3.6.5 Medical Chemical Defense Advanced Technology Development (Project TC3)

This project supports the investigation of new medical countermeasures to include antidotes, pretreatment drugs, and topical skin protectants to protect U. S. forces against known and emerging CW threat agents. Capabilities are maintained for reformulation, formulation, and scale-up of candidate compounds using current good laboratory practices. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment compounds. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Agent Exposure and Fourth Generation Agents).

3.6.5.1 TC3 Performance Goal (Outcome). The goal of the medical chemical defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for CW agents.

3.6.5.2 TC3 Outcome Measure

TC3 is minimally effective when	TC3 is successful when
<ul style="list-style-type: none"> • The results provide fundamental information and demonstrate advanced capabilities in support of new and improved defensive systems, including information on <ul style="list-style-type: none"> – chemical agent therapeutics, – chemical agent prophylaxes, – chemical agent diagnostics, – novel threat agents, – low level operational toxicology. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> • Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA.

3.6.5.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.5.4 TC3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Determine efficacy of midazolam anticonvulsant and anticholinergic drug combinations against seizures and lethality produced by all current threat agents in the guinea pig model.	<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Determine efficacy of midazolam anticonvulsant and anticholinergic drug combinations against seizures and lethality produced by all current threat agents in the guinea pig model.
<u>Nerve Agent Defense, Biological Scavenger</u> Initiate evaluation of human protein recombinant scavenger. Utilize transgenic animal model to produce adequate amounts of recombinant enzyme scavenger for preclinical testing.	<u>Nerve Agent Defense, Biological Scavenger</u> Initiate evaluation of human protein recombinant scavenger. Utilize transgenic animal model to produce adequate amounts of recombinant enzyme scavenger for preclinical testing.
<u>Nerve Agent Defense, Neuroprotection</u> Assess potential neuroprotectant treatments for nerve agent-induced brain pathology in guinea pig model.	<u>Nerve Agent Defense, Neuroprotection</u> Assess potential neuroprotectant treatments for nerve agent-induced brain pathology in guinea pig model.
<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Initiate efficacy and pharmacokinetic (PK) studies of candidate oxime(s) for use against traditional nerve agents and NTAs in non-human primates and safety/toxicity studies in two species. Continue the down selection process.	<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Initiate efficacy and pharmacokinetic (PK) studies of candidate oxime(s) for use against traditional nerve agents and NTAs in non-human primates and safety/toxicity studies in two species. Continue the down selection process.
<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> Evaluate the efficacy of candidate bioscavengers for protection against non-traditional nerve agents in multiple animal models.	<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> Evaluate the efficacy of candidate bioscavengers for protection against non-traditional nerve agents in multiple animal models.
<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Pursue development of protective agent against HD-induced skin lesions.	<u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Pursue development of protective agent against HD-induced skin lesions.
<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Begin efficacy tests of promising treatment strategies.	<u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Begin efficacy tests of promising treatment strategies.
<u>Chemical Warfare Agent Defense, Medical Diagnostics</u> Develop and test a non-invasive prototype instrument that measures blood gases via finger, ear, or toe.	<u>Chemical Warfare Agent Defense, Medical Diagnostics</u> Develop and test a non-invasive prototype instrument that measures blood gases via finger, ear, or toe.
<u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Continue development of skin and wound decontaminants for organophosphate CWAs. Continue to expand decontamination and detoxification efforts by developing HD decontaminants.	<u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Continue development of skin and wound decontaminants for organophosphate CWAs. Continue to expand decontamination and detoxification efforts by developing HD decontaminants.
<u>Chemical Warfare Agent Defense, Low Level CWA Exposure</u> Evaluate the efficacy of the FDA-approved oxime treatment, pralidoxime chloride (2-PAM), against biochemical and behavioral effects induced by repeated low level exposure to chemical warfare nerve agents in guinea pigs.	<u>Chemical Warfare Agent Defense, Low Level CWA Exposure</u> Evaluate the efficacy of the FDA-approved oxime treatment, pralidoxime chloride (2-PAM), against biochemical and behavioral effects induced by repeated low level exposure to chemical warfare nerve agents in guinea pigs.

3.6.5.5 TC3 Future Targets

FY 2005 Targets	FY 2006 Targets
<p><u>Nerve Agent Defense, Biological Scavenger</u> Complete evaluation of human protein recombinant scavenger as a nerve agent countermeasure. Initiate preparation of technical data package for transition out of the technology base.</p>	<p><u>Nerve Agent, Bioscavengers</u> Continue evaluation of catalytic bioscavenger (Block II) efficacy in animal model studies for safety and efficacy. Support studies for recombinant bioscavenger (Block II) transition to IND status. Apply an FDA license for clinical trial of h-BuChE (Block I) pretreatment. Identify delivery platforms for bioscavenger genetic material for exploration of administration via gene therapy. Determine 3-D X-ray crystallographic structure of human carboxylesterase (CaE) and PON-1. Complete testing of vector/gene combinations to validate the concept of gene therapy for bioscavengers. Perform advanced studies of in-vivo expression systems for the delivery of bioscavengers. Explore utility of peptide drugs as potential catalytic scavengers.</p>
<p><u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Initiate PK evaluations of selected antivesicants.</p>	<p><u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Continue PK evaluations of selected antivesicants.</p>
<p><u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Evaluate the efficacy of candidate treatment regimens in promoting improved healing of cutaneous sulfur mustard injuries.</p>	<p><u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Evaluate additional commercially available wound healing products in a weanling pig model.</p>
<p><u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Evaluate the ability of Sandia foam combined with wetting solutions to extract agent from under the skin and extend the time delay for effective decontamination against nerve agents, blister agents, and non-traditional agents (NTAs). Compare efficacy of RSDL with other leading skin decontamination products on skin challenge with HD, VX, and non-traditional agents (NTA). Evaluate the effectiveness of RSDL and other leading decontamination products on skin that active Topical Skin Protectant (aTSP) was applied prior to CWA. Evaluate the ability of Sandia foam combined with wetting solutions to extract agent from under the skin and extend the time delay for effective decontamination against nerve agents, blister agents, and non-traditional agents (NTAs). Compare efficacy of RSDL with other leading skin decontamination products on skin challenge with HD, VX, and non-traditional agents (NTA). Evaluate the effectiveness of RSDL and other leading decontamination products on skin that active Topical Skin Protectant (aTSP) was applied prior to CWA.</p>	<p><u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Select a replacement for the M291 SDK.</p>
<p><u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Assess application of emerging therapy for organophosphate insecticide poisoning to nerve agent exposure. Continue testing of midazolam and anticholinergic drug combinations against seizures and lethality produced by all current threat agents. Initiate PK evaluations of selected anticonvulsants.</p>	<p><u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Assess application of emerging therapy for organophosphate insecticide poisoning to nerve agent exposure.</p>
<p><u>Nerve Agent Defense, Neuroprotection</u> Initiate PK evaluations of selected neuroprotectants.</p>	<p><u>Nerve Agent Defense, Neuroprotection</u> Finish and compile data for PK evaluations of selected</p>

FY 2005 Targets	FY 2006 Targets
<p><u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Determine efficacy of oximes against selected NTAs and traditional nerve agents in non human primates and/or rabbits. Complete correlation of oxime efficacy with pharmacokinetics and AChE reactivation in guinea pigs. Complete pharmacokinetics of candidate in guinea pig and determine pharmacokinetics in non-human primate and/or rabbits. Complete safety/toxicity studies of candidate oximes in mice and guinea pigs. Complete determination of stability of oximes in aqueous solution.</p>	<p>neuroprotectants.</p> <p><u>Improved Oxime</u> Perform safety testing and dose range study for new compounds in non-human primate model.</p>
<p><u>Diagnostic Technologies</u> Perform advanced research aimed at developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Continue experiments focusing on detecting sulfur mustard exposure. Continue developing automation/high throughput strategy for cholinesterase assay. Continue development of alternate sample collection/extraction technology. Initiate lab based studies to assess the development of a genomics-based diagnostic screening test for chemical warfare agent exposure.</p>	<p><u>Diagnostic Technologies</u> Continue advanced research experiments aimed at developing detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CWA exposure. Continue experiments focusing on detecting sulfur mustard exposure. Expand studies evaluating automation/high throughput strategy for cholinesterase assay. Continue development of alternate sample collection/extraction technology. Initiate lab based studies to assess the development of a genomics-based diagnostic screening test for chemical warfare agent exposure.</p>
<p><u>Chemical Warfare Agent Defense, Low Level CWA Exposure</u> Evaluate the effects of selected pretreatment and/or therapeutic medical countermeasures, to include the FDA-approved Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP), on the detrimental actions of low dose chemical warfare nerve agent exposure in guinea pigs.</p>	<p><u>Chemical Warfare Agent Defense, Low Level CWA Exposure</u> Complete studies on the effects of chronic low dose chemical exposure and possible medical countermeasures.</p> <p><u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> DTO CB51 Completed. Complete integration studies to determine the long term medical effects of exposure to low levels of chemical agents and determine the efficacy of possible medical countermeasures.</p>
	<p><u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> DTO CB57 completed. Complete studies on the efficacy of barrier skin creams on NTA's and determine the effectiveness of current skin decon kits in treating NTA skin contamination. Determine the efficacy of oximes and human butyl cholinesterase against NTA's.</p>
	<p><u>Cyanide Pretreatments</u> Characterize physiological properties of potential anti-cyanide drug treatments. Test anti-cyanide compound efficacy in higher animal species. Test dosage and stability studies.</p>

3.6.5.6 Assessment of Medical Chemical Defense Advanced Technology Development.

Advanced technology development efforts in FY04 for project TC3 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational

goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY04.

3.6.6 Techbase Technology Transition (Project TT3)

This project supports technology transition efforts. These efforts test and demonstrate technologies being developed for transition from the Joint Science and Technology Office (JSTO) to the Joint Program Executive Officer (JPEO). This project is funded by realignment of funds: BA6, Anti Terrorism 6 funds; BA3, CB3 funds for Technology Readiness Evaluations; BA3, CP3 funds for Counter Proliferation Support Program, ACTD Planning and Development; and BA3, CM3 Homeland Defense, Civil Support Teams into it for FY06 and out. The WMD-CST group includes funds from the former CM3 project (FY05 and earlier) which funds Pre-Systems Acquisition in support of Consequence Management teams around the Nation. The technology transition project also supports Advanced Technology Demonstrations and planning for Advanced Concept Technology Demonstrations in the Experimentation and Technology Demonstration group. The Force Protection group demonstrates and tests technology for Force Protection/Installation Protection and specifically for PM Guardians Installation Protection Program. The Technology Readiness Assessment group funds testing on technologies transitioning out of the Non-medical and Medical Science and Technology programs to meet specific criteria postulated by the JPEO in Technology Transition Agreements or tests technologies provided in response to a Broad Agency Announcement in order to satisfy an acquisition strategy for a Joint Program Manager working for the JPEO.

3.6.6.1 TT3 Performance Goal (Outcome). The goal of the Techbase Technology Transition project is to support technology transition efforts and to test and demonstrate technologies being developed for transition from the Joint Science and Technology Office (JSTO) to the Joint Program Executive Officer (JPEO).

3.6.6.2 TT3 Outcome Measure

TT3 is minimally effective when	TT3 is successful when
<ul style="list-style-type: none"> Key technology testing and demonstration efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed 	<ul style="list-style-type: none"> Technologies, or processes are tested and demonstrated before transition to the JPEO.

3.6.6.3 TT3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
TT3 targets are programmed for FY06	

3.6.6.4 TT3 Future Targets

FY 2005 Targets	FY 2006 Targets
TT3 targets are programmed for FY06	<p><u>Experimentation and Technology Demonstration</u> Perform candidate technology maturation testing in preparation for the proposed FY07 ACTD candidate.</p> <p><u>Experimentation and Technology Demonstration</u> Execute the Military Applications in Reconnaissance and Surveillance (MARS) Unmanned Ground Vehicle (UGV) program testing CBRN detection technologies for use on one man and two man portable UGVs for technology insertion into the CUGR ACTD or the transition program for CUGR ACTD's UGV portion.</p>

FY 2005 Targets	FY 2006 Targets
	<p><i>Experimentation and Technology Demonstration</i> Execute the MARS Unmanned Aerial Vehicle (UAV) program testing CBRN detection technologies for use on small UAV's dedicated to CBRN passive defense or CBRN consequence management, reconnaissance and surveillance applications.</p>
TT3 targets are programmed for FY06	<p><i>Force Protection</i> Demonstrate technology for installation protection program, military postal service. Evaluate alternatives and develop system description for installation synthetic training system.</p>
TT3 targets are programmed for FY06	<p><i>Technology Readiness Assessment</i> Conduct targeted technology readiness assessments on technologies transitioning from the applied research program into . Candidates are decontamination solution formulations, stand-off chemical detection, chem-bio agent water monitor, chemical point detectors with TIC/TIM/NTA capabilities, and biological agent identifiers and triggers.</p> <p><i>Technology Readiness Assessment</i> Initiate GOTS/COTS testing to evaluate applicability of mature technologies for rapid transition to fill S&T development gaps and satisfy acquisition program requirements.</p> <p><i>Technology Readiness Assessment</i> Initiate test and evaluation process improvements that support test methodology development, standardization of test conditions and threat support data. Conduct efforts in coordination with T&E Executive for interagency coordination.</p>
TT3 targets are programmed for FY06	<p><i>WMD CST</i> Continue evaluation and testing of new commercial products being considered in response to WMD CST requirements.</p> <p><i>WMD CST</i> Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.</p> <p><i>WMD CST</i> Implement modified requirements and transition processes and continue to participate in analysis of alternatives and for follow-on technology insertion options.</p>

3.6.6.5 Assessment of Techbase Technology Transition.

Assessments for Techbase Technology Transition efforts are scheduled to begin in FY06.

4.0 CBRN DEFENSE HOMELAND SECURITY AND FORCE PROTECTION

Programs to provide CBRN defense in support of homeland security and force protection are integrated into several program elements of the DoD CBRN Defense Program. Specific efforts include programs and systems to equip the National Guard WMD Civil Support Teams, Joint Service Installation Pilot Program, and the Installation Protection Program. Descriptions of these capabilities are also provided in Annex F of the DoD CBRN Defense Program Annual Report to Congress.

4.1 WMD Civil Support Team Advanced Technology Development (Project CM3)

This project funds Pre - Systems Acquisition in support of Consequence Management teams around the Nation. National Guard Weapons of Mass Destruction Civil Support Teams (WMD CST) are being established in every state. These teams were created based upon the Defense Reform Initiative Directive #25 (DRID #25), Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction (WMD). The role of the Civil Support Teams (CSTs) were further codified in the National Security Strategy of October 1998, which builds upon the National Guard's ties to the communities throughout the nation, and its long- standing tradition of responding to national emergencies. The strategy allows the National Guard to provide forces and resources that the emergency manager requires to manage the potentially catastrophic effects of a WMD situation. The National Guard, as the lead organization for military support to local and state authorities, leverages its geographic dispersion across the nation to reduce response times, and allow for the majority of the country to be protected. As a result of Presidential and Secretary of Defense directives, the Department of Defense established the Weapons of Mass Destruction Civil Support Teams (WMD CST) to rapidly respond in support of a local incident commander to assess a suspected WMD incident scene, advise them of appropriate courses of action that will protect local populations from loss of life, injury, and significant property damage, and facilitate the development of their requests for assistance (RFAs) based on CST knowledge of available local, state and federal resources that can assist in the mitigation of a WMD emergency. This program funds the acquisition, validation and testing of commercial-off-the-shelf (COTS)/government off-the-shelf (GOTS) components on the existing Table of Distribution and Allowances (TDA) for WMD CSTs as well as those systems or components that are responsive to validated WMD CST requirements. This program also funds the evaluation of new commercial products and capabilities that may meet requirements and may be considered for the WMD CST TDA.

4.1.1 CM3 Performance Goal (Outcome).

The goal of the WMD-CST advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBRN agents.

4.1.2 Metric Description.

The metric for CM3 is focused on providing improved capabilities to the WMD Civil Support Teams. Success accomplishment of research will result in transitioning of projects to the Civil Support Teams and support of DoD's homeland security mission.

4.1.3 CM3 Actual and Planned Performance:

FY2004 Targets	Actual Performance
<i>WMD CST - Continue to evaluate Chemical / Biological detection / identification technologies for insertion into WMD CST Tables of Distribution and Allowances (TDA).</i>	Targets have been met.
<i>WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.</i>	

4.1.4 CM3 Future Targets

FY 2005 Targets	FY 2006 Targets
<p><i>WMD CST - Continue evaluation and testing of new commercial products being considered in response to WMD CST requirements.</i></p> <p><i>WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.</i></p> <p><i>WMD CST - Implement modified requirements and transition processes and continue to participate in analysis of alternatives and for follow-on technology insertion options.</i></p>	

4.1.5 Assessment of WMD-CST Advanced Technology Development.

This effort is effective. All targets have been met.

4.2 WMD-CSTs and Installation Protection (Projects CM4, CM5, CM6, and AT6)

This project funds component level testing in support of Weapons of Mass Destruction Civil Support (WMD CS) operations. Complimentary development efforts continue into CM5 for the Analytical Laboratory System (ALS) Blk I and Unified Command Suite (UCS) Increment I upgrades. This funding provides resources to successfully execute the Consequence Management RDA program. Weapons of Mass Destruction Civil Support Teams (WMD-CSTs) and U.S. Army Reserve Reconnaissance and Decontamination assets would receive the systems developed and procured under this program.

The Force Protection - CB Installation Protection Program (CBIPP) consists of a highly effective and integrated CBRN installation protection and response capability. This capability includes detection, identification, warning, information management, individual and collective protection, restoration, and medical surveillance, protection and response. The communications network will leverage existing capabilities and be integrated into the base operational command and control infrastructure. The program will develop and procure the CBRN systems, Emergency Responder Equipment Sets, New Equipment Training (NET), Contractor Logistics Support, spares, and associated initial consumable items required to field an integrated installation protection capability at 200 DoD installations (185 CONUS and 15 OCONUS).

WMD-CST - This program supports the acquisition of chemical, biological, nuclear defense equipment requirements for the National Guard Bureau's Weapons of Mass Destruction Civil Support Teams and the United States Army Reserve (USAR) Recon and Decon Platoons. The program equips: (1) WMD Civil Support Teams (CSTs) to provide on-site, rapid response

elements at the Federal, State and local levels; (2) USAR Chemical Recon and Medical Decon Platoons. Required equipment deliveries to support this effort are displayed on their respective program P-Forms. This effort will allow selected National Guard and other reserve component units to respond to and contain the effects of CB incidents in this country.

Major developmental end items for this program include the Analytical Laboratory System (ALS), and the Unified Command Suite (UCS) for the WMD CSTs. The ALS provides advanced technologies with enhanced sensitivity and selectivity in the detection and identification of chemical warfare (CW) agents, Toxic Industrial Chemicals (TICs), and Toxic Industrial Materials (TIMs). The UCS provides communication interoperability with the ALS and reachback capability to Federal, State and local Emergency Responders from the WMD incident site. Additional CB equipment sets are as follows: USAR – JSList, ICAMs, ACADAs, Mass Decon Tents, Self Contained Breathing Apparatus (SCBA), and Hazardous Material Recon Equipment Sets; NGB-WMD CST Hapsites and ACADA Simulators.

The growing threat of the use of CB agents in acts of terrorism places DoD installations and personnel at a higher risk. With that in mind, this budget item provides DoD with the means to address the threat of CB terrorism to DoD installations and personnel. It attempts to address the requirements identified in Presidential Decision Directive (PDD) 39 and PDD 62. Funding provides for the development of combating CB terrorism planning, training, and exercise technologies; and the sustainment of those technologies in the outyears, as appropriate. Sponsors of projects funded under this budget item would include DTRA, Joint Staff J-34, Assistant Secretary of Defense Special Operation Low-Intensity Conflict (ASD (SO/LIC)), United States Army Edgewood Chemical and Biological Command (ECBC), United States Army Chemical School, Fort Leonard Wood (USACMLS), the Technical Support Working Group, and other organizations involved with combating CB terrorism.

4.2.1 Actual and Planned Performance:

FY2004 Targets	Actual Performance
WMD-CST Initiate Phase II HAPSITE component testing. Initiate component level testing of commercial Level A and B ensembles. Continue development of Unified Command Suite (UCS) and ALS upgrades. Provide government engineering and planning support. Integrate test methodology development for CSTs into CBDP Test and Evaluation process. Coordinate with JPEO CBD PM Guardian for equipment, threat and operational issues. Participate in Requirements Capabilities Assessment Working Group (RCAWG) and support conduct of assessments and validation. Continue Advanced Concept Technology Demonstration (ACTD) to support system capability transition to CSTs. Develop transition plan for CBDP capabilities to PM WMD Civil Support Systems (CSS) and JPM Guardian	WMD-CST Initiated Phase II HAPSITE component testing. Initiated component level testing of Unified Command Suite (UCS) Increment I. Initiated component level testing for Analytical Laboratory System (ALS) Blk. I. Provide government engineering and planning support. Conduct component testing for CB support equipment.

FY2004 Targets	Actual Performance
consistent with CST requirements process.	
<u>Force Protection:</u> Initiate test and evaluation of emerging governmental and commercial CBRN detection, identification warning, individual and collective protection, decontamination, medical surveillance and protection technologies. Initiate independent installation evaluation assessments. Initiate software development of a CBRN knowledge base to support decision tools needed to determine installation critical CBRN requirements. Initiate an improved and lower cost biological aerosol warning system to support Dry Filter Units. System will provide improved warning of a potential biological release, supporting more rapid analysis. Initiate development and improvement of NBC warning system to support unique installation warning and reporting requirements. Engineering and technical support.	
Develop after action reports for participating installations. Refine fixed site facility biological detection concept of operations (CONOPS) to reduce life cycle costs.	

4.2.2 Future Targets

FY 2005 Targets	FY 2006 Targets
<u>WMD-CST</u> Initiate Developmental Test for UCS and ALS. Initiate Initial Operational Test and Evaluation (IOT&E) of the UCS/ALS. Continue development of UCS and ALS upgrades. Provide government engineering and planning support. Continue participation in RCAWG. Provide technical and operational support for plans. Conduct demonstration and validation exercises for CSTs. Continue development and validation of test methodologies for transition of equipment to CSTs.	
<u>Force Protection:</u> Complete test and evaluation of emerging governmental and commercial CBRN detection, identification warning, individual and collective protection, decontamination, medical surveillance and protection technologies. Complete independent installation evaluation	

FY 2005 Targets	FY 2006 Targets
<p>assessments.</p> <p>Complete software development of a CBRN knowledge base to support decision tools needed to determine installation critical CBRN requirements.</p> <p>Develop an improved, lower cost biological aerosol warning system to support Dry Filter Units. This system will provide improved warning of a potential biological release, supporting more rapid analysis.</p> <p>Develop an improved NBC warning system to support unique, installation warning and reporting requirements.</p> <p>Develop improved biological identification technologies (electro-chemiluminescence) to support laboratory operations. Improvements will support the development of a multiplex immunoassay capability thereby reducing processing time and costs.</p> <p>Initiate and complete development of improved TIC detection and identification. Focus on improved automation to reduce costs.</p> <p>Engineering and technical support.</p>	
Perform analytical support for the JSIPP and perform analysis of standardized test requirements for first responder and civilian protection equipment.	

Homeland Security and Force Protection Modernization Strategy

	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-19)
Installation Protection	<ul style="list-style-type: none"> • JSIPP and IPP to over 35 installations • GOTS/COTS: Approved for Service Use CBRN equipment and Systems 	<ul style="list-style-type: none"> • IPP to over 165 additional installations • Use of emerging subsystem advances • Advanced SBA tools 	<ul style="list-style-type: none"> • Use of automated Information Systems • Use of advanced CBRN subsystems
WMD-CSTs	<ul style="list-style-type: none"> • Equip CBRNE equipment to the standing up of 12 new NGB WMD-CSTs starting in FY04 and projected additional 11 new CSTs starting in FY 05 • Equip CBRNE equipment to the standing up of one USAR Decon Company starting in FY04 and complete in FY05 	<ul style="list-style-type: none"> • The testing and fielding of upgraded Analytical equipment for the Analytical Laboratory System (ALS) as Block I • The testing and fielding of upgraded Communications equipment in the Unified Command Suite (UCS) as Incremental I 	<ul style="list-style-type: none"> • Possible Block II for the ALS • Possible Incremental II for the UCS

DOD CBDP DEFENSE MANAGEMENT PRACTICES

5.0 OVERVIEW OF CBDP MANAGEMENT PRACTICES

In Chapter 1 of the Annual Report to Congress on the DoD CBDP, the management and oversight structure of the DoD CBBP is described. In this year's report, the reorganization of the management and oversight structure is outlined as the structure is being implemented pursuant to the Implementation Plan for the Management of the DoD Chemical and Biological Defense Program approved April 22, 2003. As the CBDP has matured over the past decade, this reorganization brings management efficiencies that will facilitate program management.

This section of the report focuses on management practices in support of **Corporate Goal 4: Improve DoD CBRN defense management practices – become a high performance organization.**

Activities in support of CBDP management activities are detailed in Budget Activity 6 (RDT&E Management Support) of the President's Budget Submission. Specific management projects (and project reference) are as follows:

- Joint Doctrine and Training Support (DT6)
- Dugway Proving Ground (DW6)
- RDT&E Management Support (MS6)
- Joint Point Test (O49)
- Small Business Innovative Research (SBIR)

5.1 CB DEFENSE MANAGEMENT PRACTICES – GOALS AND MEASURES

5.1.1 CB Defense Management and Oversight Outcome Measures

CB Defense Management and Oversight is...

...minimally effective when...	... successful when...
<ul style="list-style-type: none"> • All DoD research, development, and acquisition (RDA) efforts have documented plans that are reviewed and contribute to operational goals. • DoD RDA efforts are coordinated among the Services and Defense Agencies. • All RDA programs are issued to the field with accompanying doctrine and training to ensure their effective application. 	<ul style="list-style-type: none"> • Technologies are leveraged by other agencies to support homeland security and related missions. • Commercial or other available technologies are leveraged to accelerate the development or fielding schedule of priority programs.

5.1.1.1 Metric Description. The metric for management and oversight is a qualitative assessment. This qualitative methodology for measuring the outcomes is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. Successful oversight allows for the application of performance-based measures to ensure an appropriate balance among the complex and interrelated family of chemical and biological defense systems. The balance must be continually reviewed to ensure the appropriate mix of capabilities for contamination avoidance, protection, and restoration, and among competing missions of passive defense, force protection, and consequence management, and also among the balance of near-term needs (procurement) versus long-term technological advancements (science and technology base.) An important element of the management and oversight success is what is not accomplished. That is, it is the role of management at times to make investment decisions and select among competing technologies, sometimes eliminating technologies that may have met the operational requirements though not as effectively as selected programs, and sometimes this

means the elimination of funding for unsuccessful programs. Another key management metric is the successful coordination of research, development, and acquisition efforts among the many federal agencies pursuing similar efforts though for different missions (e.g. homeland security.)

5.1.2 Assessment of CB Defense Management and Oversight Outcome Measure

Overall, the DoD CBDP management and oversight has been effective, though many areas within the overall structure have required improvement to provide a more efficient approach. These changes are detailed in **Chapter 1** of Volume 1 of this report. Continued reports on the management and oversight process will be provided as the new structure is implemented during 2004.

5.2 CHEMICAL/BIOLOGICAL DEFENSE (RDT&E Management Support) (PROGRAM ELEMENT 0605384BP)

This program element provides research, development, testing and evaluation management support to the DoD CBDP. This effort funds joint doctrine and training support; funds sustainment of technical test capability at Dugway Proving Ground (DPG); and funds financial and program management support. Additionally, this program element funds the Joint Point Test program (O49), which provides a response to Combatant Commanders and Services regarding joint tests and research assessments. Joint Training and Doctrine Support (DT6) funds development of Joint Doctrine and Tactics, Techniques, and Procedures for developing CB defense systems. The training and doctrine efforts also fund CB modeling and simulation to support the warfighter.

Dugway Proving Ground (DW6), a Major Range and Test Facility Base, funding provides for CB defense testing of DoD materiel, equipment, and systems from concept through production; to include a fully instrumented outdoor range capability for testing with simulants that can be precisely correlated to the laboratory testing with live agents. It finances indirect test operating costs not billable to test customers, including indirect civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment.

The management support program (MS6) provides management support for the DoD CBDP to allow program overview and integration of overall medical and non-medical programs by the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ATSD(NCB)), through the Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense (DATSD(CBD)); execution management by the Defense Threat Reduction Agency (DTRA); integration of Joint requirements, management of training and doctrine by the Joint Requirements Office (JRO); Joint RDA planning, input to the Annual Report to Congress and Program Objective Memorandum (POM) development by the Program Analysis and Integration Office (PA&IO); review of joint plans and the consolidated CB Defense POM Strategy by Army in its Executive Agent role.

The management support program also funds the Joint Test Infrastructure Working Group (JTIWG) program to provide a mechanism to address test infrastructure and technologies needed to support Developmental Testing (DT) and Operational Testing (OT) of Department of Defense (DoD) CB defense systems and components throughout the systems' acquisition life cycle, as required in the RDA Plan. The JTIWG program funds a series of methodology,

instrumentation, and associated validation programs to provide test infrastructure and technologies for testing RDA systems needed to support all services.

The Joint Concept Development and Experimentation Program (O49) funds provide planning, conducting, evaluating, and reporting on joint tests (for other than developmental hardware) and accomplishment of operational research assessments in response to requirements received from the Services and the Combatant Commanders for already fielded equipment and systems.

This Budget Activity also funds the Small Business Innovative Research (SBIR) program. The overall objective of the CBD SBIR program is to improve the transition or transfer of innovative CBD technologies between DoD components and the private sector for mutual benefit. The CBD program includes those technology efforts that maximize a strong defensive posture in a CB environment using passive and active means as deterrents. These technologies include CB detection; information assessment (identification, modeling, and intelligence); contamination avoidance; and protection of both individual soldiers and equipment.

5.2.3 CB DEFENSE (RDT&E Management Support) (Project DT6 – Joint Doctrine and Training Support)

The activities of this project directly support the Joint Service CB defense program; in particular, the development of Joint CBRN defense capability requirements and the improvement of CBRN defense related doctrine, education, training, and awareness at the Joint and Service levels. This effort funds (1) development, coordination, and integration of Joint CBRN defense capability requirements; (2) development/revision of medical and non-medical CBRN defense Multi-Service Tactics, Techniques, and Procedures (MTTP), Joint Doctrine and Tactics, Techniques, and Procedures (JTTP); (3) the United States Army Chemical School Joint Senior Leader Course (USACMLS JSLC); (4) assistance in correcting training and doctrine deficiencies covered in DODIG and GAO reports; (5) support of current and planned CBRN defense studies, analysis, training, exercises, and wargames; determine overlaps, duplication, and shortfalls; and build and execute programs to correct shortfalls in all aspects of CBRN defense also all DoD mission areas.

DT6 Actual and Planned Performance

FY2004 Targets	Actual Performance
Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine: (1) NBC Aspects of Consequence Management; (2) NBC Defense of Theater Fixed Sites, Ports, and Airfields. Continue to support the integration of CB defense considerations during the revision and development of selected joint doctrinal materials. Continue support to the integration and enhancement of NBC/WMD materials in joint and service professional education. Continue support to the Combatant Commanders with NBC/WMD exercise assistance and training. Coordinate drafting/review of Joint ORDs.	Continue analyses to define capability gaps, capability needs and approaches to provide those capabilities within CBRN defense across all DoD mission areas. Initiate execution of the Joint Enabling Concept for CBRN Defense experimentation strategy. Continue analyses to support the development of joint architectures, joint operational concepts, and supporting technical annexes. Continue development, coordination and integration of joint capability requirements.

FY2004 Targets	Actual Performance
Continue analyses to support the definition phase of the requirements generation process, joint operational concepts, architecture development, and supporting technical annexes: (1) Toxic Industrial Materials prevalence in Areas of Responsibility on Operations and Tactics for Major Theaters of War and Military Operations other than War; (2) Operational factors affecting protective prophylaxis and pretreatment; (3) Standoff range optimization to support surveillance, reconnaissance, survey, and monitoring capabilities.	Initiated the revision and development of the MTTP for CBRN Defense Operations. Continued to support the integration of CBRN defense considerations during the revision and development of selected joint doctrine and JTTPs.
Continue to support additional joint participation in the Joint Senior Leaders' Course (JSLC).	Continued to support additional joint participation in the JSLC.
Continue support of Services Battle Management requirements. Continue to define the requirements for simulation based virtual CBD environment to training, mission planning/rehearsal, force development, and acquisition programs. Validate modeling and simulation requirements and tools for C4I systems.	Continued to provide assistance in the development and enhancement of CBRN defense curriculum and wargaming at intermediate and senior level Joint and Service colleges and senior Service non-commissioned officer academies. Continued assistance and support for providing CBRN defense related improvements to the four phases of the Joint Training System at Combatant Commands. Continued to provide assistance in the implementation of required solutions for appropriate representation of CBRN defense in Combatant Command's modeling and simulation tools. Continued to provide CBRN defense related training support to Combatant Command staffs, services and the USCG.

DT6 Future Targets

FY 2005 Targets	FY 2006 Targets
Continue to provide assistance in the development and enhancement of CBRN defense curriculum and wargaming at intermediate and senior level Joint and Service Colleges and Senior Service Non-Commissioned Officer Academies. Continue assistance and support for providing CBRN defense related improvements to the four phases of the Joint Training System at Combatant Commands. Continue to provide assistance in the implementation of required solutions for appropriate representation of CBRN defense in Combatant Command's modeling and simulation tools. Continue to provide CBRN defense related training support to Combatant Command staffs, services and the USCG.	Continue to provide assistance in the development and enhancement of CBRN defense curriculum and wargaming at intermediate and senior level Joint and Service Colleges and Senior Service Non-Commissioned Officer Academies. Continue assistance and support for providing CBRN defense related improvements to the four phases of the Joint Training System at Combatant Commands. Continue to provide assistance in the implementation of required solutions for appropriate representation of CBRN defense in Combatant Command's modeling and simulation tools. Continue to provide CBRN defense related training support to Combatant Command staffs, services and the USCG.
Continue to support the revision and development of CBRN defense medical and non-medical MTTPs: (1) CBRN Aspects of Consequence Management; (2) CBRN Defense of Theater Fixed Sites, Ports, and Airfields; (3) Health Service Support in an CBRN Environment; (4) CBRN Health Service Support in Homeland Defense; (5) Treatment of Biological Warfare Agent Casualties. Continue to support the integration of CBRN defense considerations during the revision and development of selected joint doctrine and JTTPs.	Continue to support the revision and development of CBRN defense medical and non-medical MTTPs. Continue to support the integration of CBRN defense considerations during the revision and development of selected joint doctrine and JTTPs.
Continue to support additional joint participation in the JSLC.	Continue to support additional joint participation in the JSLC.

FY 2005 Targets	FY 2006 Targets
Continue analyses to define capability gaps, capability needs and approaches to provide those capabilities within CBRN defense across all DoD mission areas. Continue execution of the Joint Enabling Concept for CBRN Defense experimentation strategy. Continue analyses to support the development of joint architectures, joint operational concepts, and supporting technical annexes. Continue development, coordination and integration of joint capability requirements.	

5.2.4 CB DEFENSE (RDT&E Management Support) (Project DW6 – Dugway Proving Ground)

Project provides the technical capability for testing DoD CB defense materiel, equipment, and systems from concept through production. It finances a portion of the required institutional test operating costs. Institutional test operating costs include institutional civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment.

DPG, a Major Range and Test Facility Base (MRTFB), is the reliance center for all DoD CB defense testing and provides the United States' only combined range, chamber, toxic chemical lab, and bio-safety level three test facility. Total institutional test operating costs are to be provided by the service component IAW DoDD 3200.11.

DPG uses state-of-the-art chemical and life sciences test facilities and test chambers to perform CB defense testing of protective gear, decontamination systems, detectors, and equipment while totally containing chemical agents and biological pathogens. DPG also provides a fully instrumented outdoor range capability for testing with stimulants that can be correlated to the laboratory testing with live agents.

The current level of institutional test operations funding requires that institutional costs continue to be passed to the program managers and acquisition programs. Passing institutional shortfall costs to the test customers will continue to result in increased test costs to an even greater degree than already exists. Increased test costs put critical developmental testing of CBD systems at risk of being deferred or eliminated, creating an overall increased risk for the decision-makers. Failure to fully fund the institutional portion of the developmental test mission will result in insufficient developmental testing for system reliability, performance, and safety issues and failures in operational testing. Preservation of critical Test and Evaluation (T&E) workforce and expertise is also at risk.

The current level of modernization/revitalization funding at DPG increases the risk that some essential test facilities will not be available when needed to meet CB program test schedules. Readiness and condition of test ranges and laboratory equipment will be inadequate to meet the demand of testing state-of-the-art CBD program systems and supporting technologies. Test customers will be required to redirect program funds to upgrade DPG's test facilities. This redirection of program funds puts critical T&E of CBD systems at risk of being deferred or eliminated creating an overall increased risk to the CBDP. The need to refurbish or modernize a given test fixture or series of instrumentation in a given year results in test schedule slippage to subsequent years, thus impacting acquisition program milestones.

Projects programmed for testing at DPG include: Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD); Joint Service Lightweight Nuclear Biological Chemical Reconnaissance System (JSLNBCRS); Joint Service Lightweight Integrated Suit Technology (JSLIST); JSLIST Block II Glove Upgrade; Joint Biological Point Detection System (JBPD); Joint Chemical Agent Detector (JCAD); Joint Service Sensitive Equipment Decontamination (JSSED); Technical Readiness Evaluation for Biological Stand-off Detection Systems; Joint Service General Purpose Mask (JSGPM); Artemis Chemical Stand-off Detector; Joint Protective Aircrew Ensemble (JPACE); and Joint Biological Stand-off Detection System (JBSDS).

DW6 Actual and Planned Performance

FY2004 Targets	Actual Performance
Provides for civilian labor and other supporting costs that are not directly identifiable to a specific test customer. These civilian personnel perform administration and staff support for DPG's CB test mission to include budget, surety operations, range control, Contract Officer Representative (COR) duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.	Supported a portion of the overhead costs of the civilian labor costs for Army Program Budget Guidance (PBG) authorizations. The balance was reimbursed from test customer funds. These civilian personnel supported DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provided the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.
Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.	Supported a portion of the overhead costs of the contractor labor costs. The balance is reimbursed from test customer funds. This was the institutional portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.	Provided for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes purchases to upgrade/replace aging equipment.	Provided for revitalization/upgrade efforts at DPG commensurate with technology/facility requirements for future testing. Efforts include decontamination pad replacement chemical and biological simulant characterization, chemical and biological laboratory equipment, and purchases to upgrade/replace aging equipment and instrumentation.

DW6 Future Targets

FY 2005 Targets	FY 2006 Targets
Support a portion of the overhead costs of the civilian labor costs for Army PBG authorizations. The balance is reimbursed from test customer funds. These civilian personnel support DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.	Support a portion of the overhead costs of the civilian labor costs for Army Program Budget Guidance (PBG) authorizations. The balance is reimbursed from test customer funds. These civilian personnel support DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.

FY 2005 Targets	FY 2006 Targets
Support a portion of the overhead costs of the contractor labor costs. The balance is reimbursed from test customer funds. This is the institutional portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by institutional funds; the balance is recouped from customers.	Support a portion of the overhead costs of the contractor labor costs. The balance is reimbursed from test customer funds. This is the institutional portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by institutional funds; the balance is recouped from customers.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.	Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/upgrade efforts at DPG commensurate with technology/facility requirements for future testing. Efforts include: chemical protective mask test fixture upgrades; chamber agent monitoring methodology developments; Polymerase Chain Reaction analysis improvements; and purchases to upgrade/replace aging equipment and instrumentation.	Provides for revitalization/upgrade efforts at DPG commensurate with technology/facility requirements for future testing. Efforts include: improved man-in-simulant test fixture; real-time swatch sampling methods; an aerosol exposure chamber; novel agent testing methods; and purchases to upgrade/replace aging equipment and instrumentation.

5.2.5 CB DEFENSE (RDT&E Management Support) (Project MS6 – RDT&E Management Support)

This project provides management support for the DoD CBDP. It includes program oversight and integration of overall medical and non-medical programs by the ATSD(NCB) defense programs through the DATSD(CBD), and the Director, DTRA. Funds execution management is provided by DTRA.

The project also funds development, coordination and integration of joint CBRN defense capability requirements, including assistance and support to the Combatant Commanders and Services to improve CBRN defense related doctrine, education, training, and awareness by the Joint Requirements Office (JRO) Joint CBRN defense Research, Development, and Acquisition (RDA) planning, input to the CBD Annual Report to Congress, and program guidance development by the Program Analysis and Integration Office (PA&IO).

The project includes programming support for the Joint Service CB Information System (JSCBIS) which serves as a budgetary and informational database for the DoD CBDP. Funding is provided for the CB Archive Information Management System (CBAIMS) a means to collect, assemble, catalog and archive CBD information from multiple service locations into a central repository and library.

Funding is also provided for the Test and Evaluation (T&E) Executive IPT, which serves as a mechanism to identify, develop, and manage test infrastructure and technology programs to support Developmental Testing (DT) and Operational Testing (OT) of DoD CBD systems, as outlined in the RDA Plan. The T&E Executive will fund a series of methodology, instrumentation, and associated validation efforts to provide test infrastructure and technologies for testing RDA systems needed to support all services.

Test infrastructure and technology programs have been prioritized in accordance with the RDA Plan and the annual NBC Joint Priority List (JPL). Programs will be structured to phase

highest priority efforts in time to support RDA Plan required tests and schedules to the fullest extent possible.

Test Operating Procedures (TOPs) will be developed to standardize and document new test procedures and/or to update existing test procedures. All test infrastructure and technology programs will be centrally managed and coordinated with the Joint Service community to ensure that all Services' test and acquisition program needs are met.

MS6 Actual and Planned Performance

FY 2004 Targets	Actual Performance
<i>CBAIMS</i> Archive Chemical and Biological information from multiple service locations.	<i>CBAIMS</i> Archived Chemical and Biological information from multiple service locations.
<i>JRO MGT</i> Represent the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Plan, coordinate and execute the development and review of: Joint CBRN defense capability requirements; DoD CBDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.	<i>JRO MGT</i> Represented the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Planned, coordinated and executed the development and review of: Joint CBRN defense capability requirements; Joint Staff Combating WMD Enhanced Planning Process; CBDP program guidance; DoD CBRND Program Objective Memorandum; Joint CBRND Concept; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.
<i>PA&IO MGT</i> Develop assessments to support RDA Planning. Provide analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the President's Budget (PB) submissions. Respond to specialized evaluation studies throughout the Planning, Programming, Budgeting and Execution (PPBE) process. Provide JSCBIS database management.	<i>PA&IO MGT</i> Developed assessments to support RDA Planning. Provided analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the President's Budget (PB) submissions. Responded to specialized evaluation studies throughout the Planning, Programming, Budgeting and Execution (PPBE) process. Provided JSCBIS database management.
<i>JTIWG</i> Initiate and conduct test methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Initiate planning, modeling, and development of an Interim Chemical Agent Active Standoff Detection Test Fixture.	<i>JTIWG</i> Initiate test methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Conducted yearly CBDP T&E Review and a series of work groups to define T&E capabilities needs and to resolve JPE acquisition T&E issues. Provided T&E segments to CBDP Annual Report and to POM and EPP processes.
<i>OSD MGT</i> Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.	<i>OSD MGT</i> Performed program reviews/assessments, provided programmatic PPBE oversight/analysis, provide congressional issue analysis and support. Supported financial management services provided by the DTRA such as funding distribution; quarterly financial statements and annual audits; and execution reporting. Provided JSCBIS database support.

MS6 Future Targets

FY 2005 Targets	FY 2006 Targets
CBAIMS - Archive Chemical and Biological information from multiple service locations	
<i>JRO MGT</i> Represent the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Plan, coordinate and execute the development and review of: Joint CBRN defense capability requirements; DoD CBDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.	<i>JRO MGT</i> Represent the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Plan, coordinate and execute the development and review of: Joint CBRN defense capability requirements; DoD CBDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.
<i>JTIWG</i> Continue methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Refine methodology for data fusion and visualization. Procure additional ground truth instrumentation and initiate mobile capability. Expand participation in system IPTs to plan and execute structured programs for acquisition of T&E capabilities. Provide input to JCBIS, POM annual CBDP Congressional Report. Support DOT&E in oversight of key CBDP systems.	<i>JTIWG</i> Continue methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Refine methodology for data fusion and visualization. Procure additional ground truth instrumentation and initiate mobile capability. Expand participation in system IPTs to plan and execute structured programs for acquisition of T&E capabilities. Provide input to JCBIS, POM annual CBDP Congressional Report. Support DOT&E in oversight of key CBDP systems.
<i>PA&IO MGT</i> Develop assessments to support RDA Planning. Provide analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the PB submissions. Respond to specialized evaluation studies throughout the PPBE process. Provide JSCBIS database management.	<i>PA&IO MGT</i> Develop assessments to support RDA Planning. Provide analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the PB submissions. Respond to specialized evaluation studies throughout the PPBE process. Provide JSCBIS database management.
<i>OSD MGT</i> Perform program reviews/assessments, provide programmatic PPBE oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.	<i>OSD MGT</i> Perform program reviews/assessments, provide programmatic PPBE oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support

5.2.6 CB DEFENSE (RDT&E Management Support) (Project O49 – JOINT CONCEPT DEVELOPMENT AND EXPERIMENTATION PROGRAM)

The objectives of the Joint Concept Development and Experimentation (JCDE) program are to plan, conduct, evaluate, and report on joint tests and experiments (for other than developmental hardware) and accomplish operational research assessments in response to requirements received from the Combatant Commanders and the Services. This program will provide ongoing input to the Combatant Commanders and Services for development of doctrine, policy, training procedures, and feedback into the RDT&E cycle.

O49 Actual and Planned Performance

FY2004 Targets	Actual Performance
Conduct assessments, laboratory and field tests evaluating performance and procedures in a chemical and biological environment in support of information requirements submitted by Combatant Commanders and Service representatives.	JCDE - Established the Joint Combat Developer (JCD) for CBRND at the U.S. Army Chemical School (USACMLS) to explore, develop and transition new technologies, concepts and organizational ideas that update and improve the Joint CBRND concept through work shops, studies, war games and limited objective experiments.
Conduct field tests evaluating performance and procedures in a chemical environment, to wit, the effectiveness of the C- 17 cargo aircraft in- flight checklist procedure for eliminating smoke and fumes.	Initiated field tests to evaluate performance and procedures for processing cargo and personnel through an exchange zone (Phase IV).
	Initiated analysis of current procedures to identify risks, capability shortfalls, and provide recommendations to prevent CBRN contamination of military mail.
Conduct field tests to determine the level of incursion and condensation of chemical warfare agent vapors into tunnels and other underground structures.	
Conduct laboratory and field tests evaluating use of cargo covers made from various materials for equipment protection in a chemical or biological environment.	Initiated laboratory and field tests to develop operational parameters and determine the impact of wind speed on aerosol penetration of the Joint Service Lightweight Integrated Suit Technology (JSLIST).
Continue to conduct Technical Data Source Book updates by reviewing the literature and updating volumes of the source books with newly published material.	

O49 Future Targets

FY 2005 Targets	FY 2006 Targets
<i>JCDE</i> Continue to support the JCD for CBRND in conducting work shops, studies, war games and limited objective experiments to explore, refine, and validate potential solutions and alternatives that will update and improve the Joint CBRND concept.	<i>JCDE</i> Continue to support the JCD for CBRND in conducting work shops, studies, war games and limited objective experiments to explore, refine, and validate potential solutions and alternatives that will update and improve the Joint CBRND concept.

5.2.7 CB DEFENSE (RDT&E Management Support) (Small Business Innovative Research (SBIR))

The CBD SBIR program is used to elicit innovative solutions from the small business community that address chemical and biological defense technology gaps confronting DoD and to include technologies that will also have high commercialization potential in the private sector. SBIR topics are developed in each of the following capability areas to address both chemical and biological threats: detection; protection (individual and collective); decontamination; modeling & simulation; and support science (6.1 R&D). Additionally, specific program areas include chemical and biological defense medical technologies that address pre-treatments, therapeutics; diagnostics; and emerging threats.

The Defense Threat Reduction Agency (DTRA), Chemical and Biological Defense Directorate, provides technical and programmatic oversight to SBIR topic generation in addition to proposal evaluation and selection. The Army Research Office-Washington (ARO-W) administers the day-to-day administrative activities of the CBD SBIR program and is responsible for the operation of the CBD SBIR Program Management Office.

The SBIR program was established by Congress in 1982, to permit small businesses (<500 employees) to develop and to speed the conversion of their research and development into new commercial products. SBIR allows smaller companies the opportunity to test high-risk theories and develop innovative technologies. The CBD SBIR program began soliciting proposals in 1998. Public Law 106-554, Small Business Reauthorization Act of 2000, extends the SBIR program through September 30, 2008.

All companies start at Phase I of a two-phase program. Phase I permits the firm to establish the feasibility and technical merit of a proposed innovation. A Phase II contract focuses on development of a pre-production prototype based on the proof-of-concept demonstrated during Phase I. Phase III establishes the commercialization and manufacturing of the completed technology development.

SBIR proposals are competitively evaluated based on their scientific and technical merit, and on the basis of their originality. Federal scientists or engineers that are subject matter experts for a particular topic area provide the review. Evaluation and assessment criteria include the technical merit of the proposal, qualifications of the principal investigator and key staff, potential commercial applications (dual-use technology), and, in the case of the CBD SBIR program, the benefits provided to the warfighter. Limited improvements do not get awarded SBIR funds; only products with a leap in capability providing next-generation capabilities are acknowledged.

5.2.7.1 SBIR Performance Goal (Outcome). The goal of the CB defense SBIR program is to transfer innovative CBD technologies between DoD components and the private sector for mutual benefit in all areas of CBD research.

5.2.7.2 SBIR Outcome Measure

SBIR is minimally effective when	SBIR is successful when
<ul style="list-style-type: none"> Contracts are awarded that demonstrate proof-of-principle or increase scientific understanding of CB defense technology research needs. 	<ul style="list-style-type: none"> SBIR efforts support the demonstration of technology objectives. SBIR efforts support the transition of research efforts from the science and technology base to advanced development.

5.2.7.3 SBIR Performance. Since SBIR efforts represent a contracting process rather than a goal in itself, the targets for future years are determined based on the progress of research in ongoing and planned research areas. SBIR topics are updated every six months and reflect a broad range of CBD research activities. Following are CBD SBIR data for FY03 and FY04.

CBD SBIR FY03 Statistics:

In FY03, 20 CBD SBIR topics were published on 1 October 2002, as solicitation for Phase I proposals. A record number of proposals – 347 – were submitted in response to those topics, with 25 Phase I contracts being executed having a total value of \$1.9M. Ten new Phase II contracts were also awarded in addition to funding eleven ongoing (pre-FY03) Phase II development efforts. These CBD SBIR R&D efforts span both biological and chemical defense requirements and address technology gaps in all medical and non-medical CBD capability areas.

CBD SBIR FY04 Statistics:

Phase I SBIR topics were evaluated for relevancy to technical need and mission requirements prior to public release. From 271 proposals submitted in response to twenty published topics, an estimated 25 Phase I awards with a total value of \$1.75M will be issued during 3QFY04.

Approximately 13 (estimated) successfully completed Phase I contracts will transition to Phase II, in addition to continued funding for ten ongoing (in-progress) Phase II contracts. Phase II contracts will account for approximately \$8.95M FY04 CBD SBIR funds. Prototypes delivered at the conclusion of the Phase II period-of-performance will be assessed for their ability to meet CBD program requirements and allow for transition of new technologies to the warfighter.

5.2.7.4 Assessment of SBIR. CBD SBIR efforts have been successful in FY03 and are projected to be in FY04, based on the large number of proposals received, contracts awarded, SBIR efforts transitioned to SBIR Phase II, and technologies leveraged to advanced key CB defense science and technology programs.